HANDMADE VERSES COMPUTER - AIDED DESIGN ORTHOTICS FOR REALIGNMENT OF PES PLANUS: A COMPARITIVE STUDY

A research dissertation presented to the

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DECLARATION

I declare that this research dissertation is my own, unaided work. It is being submitted for the Degree of Master of Technology at the University of Johannesburg, Johannesburg. It has not been submitted before for any degree or examination in any other Technikon or University.

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Signature of candidate

_____ day of 2021

ABSTRACT

Foot orthotics are functional devices designed to correct and optimize foot function. Amongst various treatment options available for pes planus, custom foot orthoses are currently recognised as the gold standard of treatment. Anecdotal evidence suggests that most practising podiatrists in South Africa are prescribing and manufacturing traditional handmade orthotics compared to CAD/CAM orthotics for pes planus deformity. This advanced technology is costly in South Africa and is limited by the suppliers as most suppliers are abroad. A critical drawback of CAD/CAM systems is that they are generally expensive given the small group of specialized podiatrists they are aimed at.

Studies have been undertaken abroad to determine the variations of orthotics produced by traditional methods and advanced technology. However, until this study, there have been no studies in South Africa that have investigated the efficacy of handmade orthotics compared to CAD/CAM orthotics. This study used a cross-sectional, experimental design. The aim was to compare the differences in the realignment of pes planus between traditional handmade foot orthotics and Computer-Aided fabricated orthotics.

This study had a sample of 50 participants diagnosed with functional pes planus. The researcher measured Navicular drop (N.D) in millimetres (mm), which had provided the degree of malalignment in each foot. Thereafter, each participant had a pair of handmade and CAD/CAM orthotics manufactured. N.D was then re-measured for each participant standing on their pair of handmade and CAD/CAM devices.

In the results of this study, in 80% (40/50) of participants handmade orthoses had successively realigned both feet, which meant that N.D values were realigned to normal values for both the left and the right foot. However, amongst 20% (10/50), participants had N.D values that remained abnormal, meaning that for 20% of the participants, the orthoses failed to realign both feet. In fact, of these 10 participants, 6/10 (12%) participants had both their feet remain misaligned, which meant these orthoses failed to correct both feet. In 3/10 (6%), participants had their left foot realigned to normal N.D values, but their right foot remained in abnormal N.D values

(misaligned). Lastly, 1/10 (2%) of the participants had both their feet overcorrected, meaning that the orthoses had changed both feet in a completely different position/ pathology.

The findings indicated for CAD/CAM orthotics were precise compared to handmade orthotics. This novel approach of manufacturing orthotics would be accurate in achieving normal N.D. limits, and that realignment would be achieved significantly. The findings show that 100% of participants (50/50) had N.D. within normal limits achieved by CAD/CAM orthotics for both feet. In fact, the realignment achieved by CAD devices was better than handmade devices. It was noted that none of the participants' feet remained in abnormal N.D limits, nor were any feet overcorrected.

DEDICATION

I dedicate this work to my family and the Podiatry profession.

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CHAPTER ONE: BACKGROUND AND CONTEXT

1.1 Introduction

This chapter outlines the background and context of the study, which aimed at comparing handmade and computer-aided design/manufacture (CAD/CAM) foot orthotics with regard to the effect on the realignment of functional pes planus deformity. Firstly, the problem statement, research question, study objectives, and thereafter the research design and methodology are briefly described. A more detailed description of the research design and method are presented in Chapter 3.

1.2 Background

At the time of this study, the researcher was an academic and a clinician with a private and public sector background. In her years of clinical practice, dealing with various cases of pathomechanics, the common pathology would be functional pes planus deformity, in which orthotic therapy is deemed the most suitable treatment option. The common use of orthotics to treat functional pes planus led to the researcher's areas of interest in foot pathomechanics and orthotic therapy.

Foot orthotics are functional devices designed to correct and optimize foot function (Gatt, Formosa & Chockalingam., 2016). Orthotics are available in forms of traditionally handmade orthotics, computer-aided design/manufactured foot orthotics (CAD/CAM orthoses), and prefabricated orthotics. However, custom foot orthoses are currently recognised as the gold standard amongst various treatment options available for pes planus (Dombroski, Balsdon & Froats., 2014).

The most common method of manufacturing orthoses remains the traditional handmade method. However, in recent years, technology has emerged permitting the use of computer-aided fabrication for custom foot orthoses.

In private practice, the researcher was privileged to prescribe and manufacture CAD/CAM orthotics. In contrast, in the Public sector, CAD/CAM orthotics were never an option, merely due to high costs that could never be met in an institution faced

with budgetary constraints. Within both environments, the patients presenting with functional pes planus received an orthotic device; the only difference was the methods used to manufacture the final product.

Anecdotal evidence suggests most podiatrists in South Africa (SA) prescribe and/ or are manufacturing traditional handmade orthotics as compared to CAD/CAM orthotics for the realignment of functional pes planus deformity.

Literature describes various advantages and disadvantages around both manufacturing methods. Being the advanced manufacturing method, CAD/CAM provides greater accuracy, increased quality, a less wasteful process, and most importantly, provides a faster turnaround time, benefitting the patient (Gatt *et al*., 2016). This advanced technology remains costly in South Africa, possibly due to the limited number of local suppliers. Therefore, an important drawback of CAD/CAM systems is that they are generally expensive, making them unattainable for most podiatrists.

The traditional approach of manufacturing is an unpleasant experience for patients during the cast impression. It frequently requires the process to be repeated if the orthotics have a poor fit on the foot. The handmade process of manufacturing custom orthoses is time consuming and results in material wastage (Fantin et al., 2017). However, the biggest drawback of this method is that it requires extensive technical ability, which is not consistant among podiatrists and might lead to the risk of manufacturing errors and poor orthotic fit.

Several studies have been undertaken abroad to determine variations between orthotics produced by traditional methods and those by advanced technology. However, these studies have suggested that variations might exist due to the lack of empirical data describing orthotics manufactured by both manufacturing methods in South Africa. Thus, in-depth, evidence-based knowledge in this domain remains limited and challenging.

1.3 Background to the research problem and problem statement

Prior to this study, there was no data emanating from the South African podiatry domain describing the effectiveness or the ineffectiveness of traditional handmade or CAD/CAM orthotics on the realignment of common foot pathologies such as functional pes planus. Therefore, it remains unclear whether there are any variations in the effectiveness of orthotics fabricated using the two methods. Suppose any variations exist between orthotics fabricated using the two manufacturing methods. In that case, such data is essential in providing additional evidence for appropriate orthotic intervention for the realignment of functional pes planus.

1.4 Research question

Given the problem described above, the research question was; “Are there variations between handmade and CAD/CAM orthotics concerning the effect on the realignment of functional pes planus deformity?”

1.5 Aim/s

This study aimed to investigate, document and compare handmade and CAD/CAM orthotics with regard to the effectiveness in the realignment of functional pes planus deformity.

1.6 Study Objectives

The study objective was to determine if any significant differences exist between the degree of realignment achieved by traditional handmade orthoses versus CAD/CAM orthoses amongst patients with functional pes planus deformity.

1.7 Possible Benefits

This study's results will provide initial evidence-based findings related to orthotic intervention and the method of orthotic manufacture in South Africa (SA). The results of the study may provide additional reference for the provision of appropriate orthotic intervention for the realignment of functional pes planus; highlighting the differences,

if any, in the effectiveness of traditional handmade orthotics and CAD/CAM orthotics in the realignment of functional pes planus and lastly, highlighting the need for further studies in this area.

1.8 Research design and method

In order to address the research question, a cross-sectional, descriptive design was selected for this quantitative methods study. The design and methods that were selected were considered best suited for the study. In support of this, literature describes a cross-sectional study design as a type of observational study design, one in which the researcher follows the study participants to access the exposures and outcomes in the study participants at the same time. It also provides information about the prevalence of outcomes and exposures in a population (Setia, 2016).

Hence, the study method used was cross-sectional. It investigated and documented differences between handmade and CAD/CAM orthotics in the realignment of functional pes planus deformity by comparing the degree of realignment achieved by both manufacturing methods.

The study was also descriptive in nature as it describes the similarities and/or differences (Creswell, 2013) between handmade and CAD orthotics by comparing the degree of realignment of functional pes planus deformity achieved by using both manufacturing methods. The primary purpose of this type of design is to determine the relationship between variables (Cantrell, 2011).

According to Allen (2017), the purpose and use of quantitative research is to generate greater knowledge, create clearer understanding, and observe phenomena affecting individuals within the same study. Quantitative methods are selected to test objective theories (Creswell, 2013); in this study, measuring the degree of realignment of functional pes planus deformity was achieved by comparing two orthoses manufacturing methods, these variables were measured so that numerical data can be analysed statistically and allowed the researcher to understand the relationship among the variables (Allen,2017).

A more detailed description with elaborations for the selected study design and method is presented in Chapter 3.

1.9 Outline of this study Chapters to follow

Chapter 1 outlined the background and context of this study, which aimed to compare handmade and computer-aided design/manufactured foot orthotics (CAD/CAM) with regard to the effect on the realignment of functional pes planus deformity. Firstly, the problem statement, followed by the research question and study objectives, and lastly, the research design and methodology briefly described.

In Chapter 2, the literature review discusses pes planus, clinical assessment methods, and orthotic therapy with emphasis on the use of handmade versus computer-aided orthotics in the management of functional pes planus.

Chapter 3 provides a detailed description, including explanations for the research design and methods applied to collect, analyse and interpret data related to the aim and objectives of this study. This chapter concludes by discussing ethical considerations applicable to this study.

Chapter 4 presents the results of this cross-sectional, descriptive design study, which entails non-parametric statistics presented descriptively in the form of pie charts, graphs, and tables.

Chapter 5 discusses this study's findings; this discussion is based on the results presented in Chapter 4 and literature used to support these findings.

Chapter 6 concludes and summarises this study and its limitations before providing some recommendations for further research and future practise.

1.10 Summary

This Chapter has described the background, objectives, and purpose of this study, which investigated the variations between handmade and CAD/CAM orthotics with

regard to the effect on the realignment of functional pes planus deformity. Also included in this Chapter was a brief description of the research design and methodology. The following Chapter will present a Literature Review undertaken for this study.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

A literature review aims to orient the researcher to understand what already exists on a problem to be studied and what is not known and then to decide whether the existing knowledge applies to the current study (Creswell, 2018). The literature review in this study was essential to frame the study within the context of the management of functional pes planus, clinical assessment methods, and orthotic therapy with an emphasis on the use of handmade versus computer-aided orthotics.

Anecdotal evidence suggests that most South African Podiatrists prescribe handmade orthotics for the management of functional pes planus. However, there have been no studies done in South Africa on the use of orthotics in the management of pes planus. Therefore, the literature review has highlighted various studies undertaken abroad. The literature sourced for this study was sought from books and various journals such as *The Foot; Foot & Ankle Surgery; Foot & Ankle International; Professional Medical Journal: SAGE publications*, which were available on the University of Johannesburg's library database. The following key words/ search terms were utilised: *pes planus, CAD/CAM orthotics and handmade orthotics.*

2.2 Structural anatomy of pes planus

Pes planus is an anatomical alteration that can occur in one foot (unilateral pes planus) or both feet (bilateral pes planus). The most common structural difference in flatfeet is found to be rear-foot varus, which in turn causes excessive pronation of the foot. In addition, a deepened navicular cup, widened talus articular surface, proximally faced talus, and higher positioned navicular articular surface can be seen. These alterations cause the medial longitudinal arch (MLA) to collapse, resulting in a loss of arch height. When this loss of arch height is observable in both non-weight bearing and weight-bearing positions, it is known as rigid flatfeet. Contrarily, when an average MLA height is present in non-weight bearing condition and collapses with weight-bearing, it is identified as flexible flatfeet.

Pes planus occurs from a partial or complete collapse of the arch. Functional pes planus is the most common type in which the foot is flat on standing and returns to a

normal arch in weight-bearing positions. A pressure absorption mechanism defect characterises pes planus foot during walking. It includes several deformities that may be more or less severe such as the collapse of the medial arch, rearfoot eversion, and abduction and supination of the forefoot. Pes planus feet are associated with pronation.

Pronation is a normal and essential motion of the foot. It allows the foot to act as a mobile adapter over uneven ground and helps attenuate the shock of ground contact. Excessive or abnormal pronation occurs when the foot continues to pronate throughout gait (beyond midstance) at a period when supination should be occurring. Excessive pronation results in excessive or prolonged internal tibia rotation, leading to the forces applied to the lower limb in a potentially harmful manner.

Range of motion evaluation differentiates the flexible from rigid flatfoot and identifies the degree of abnormal motion that may be present. Additionally, the Hubscher manoeuvre (Jack test) is used to determine pes planus flexibility. Manual muscle testing and the single heel-rise test assess muscle strength and tendon function. Additionally, the double heel-rise test determines the reducibility of rearfoot valgus. Gait observation may show an increased angle of gait, delayed or absent supination of the foot, or decreased propulsion. Footwear patterns can also provide valuable information.

2.3 Functional Pes planus

2.3.1 Definition

Pes planus is a common foot pathology, also referred to as a flat foot. It is a postural appearance of the foot, with a collapsed medial longitudinal arch and a pronated subtalar joint (Dare, Onyije & Osoma., 2012). Banwell *et al* (2015) states that pes planus is characterised by a loss of medial longitudinal arch height as shown in “Figure 1” and is often associated with rearfoot eversion, foot malalignment, instability of the medial foot structure, and an altered gait pattern (Chen, Lou, Huang & Su., 2010).

Figure 1 Pes Planus (Menz H, 2008)

2.3.2 Classification of Pes Planus

Pes Planus deformity (flat foot) is classed into two types, namely functional or rigid (Raj, Tafti & Kiel.,2019). Functional or flexible pes planus appears as a standard arch height in a non-weight bearing position; however, a significant collapse of the medial longitudinal arch is noted when bearing weight (Raj *et a*l., 2019). Raj (2019) further states that flexible pes planus is associated with ligament laxity allowing the arch to collapse when weight is applied. Rigid pes planus is a rare deformity that often occurs because of the tarsal coalition. Rigid pes planus might result from the progression from flexible to rigid pes planus as part of the ageing process or other forms of congenital hindfoot pathology. In a rigid pes planus foot, there is the rigidity of the medial longitudinal arch, which causes a collapsed arch seen in both non-weight bearing and weight-bearing. Accentuating the arch by passive dorsiflexion of the first toe or by standing on tiptoe is impossible in a rigid pes planus foot (Raj *et a*l., 2019).

2.3.3 Epidemiology of Pes Planus

The prevalence of flat foot is not well defined in South African literature; however, one unpublished study found that black African males have a higher incidence of flat feet (Erasmus & Ntuli, 2016). The mentioned study had a limited number of participants to generalise its findings effectively. Studies conducted abroad, such as

Dunn et al. (2004), found that the prevalence among non-Hispanic whites was 17% and higher among African Americans at a rate of 34%; there is a 1: 1 ratio of men to women and an active genetic component as it typically is familial.

Aenumulapalli et al. (2017) conducted another study to determine the prevalence of flexible flat foot among 18-21 -year -old Indian adults using the Navicular Drop Test, it was found that pes planus in 12.8% were male and 14.4% were females. Similarly, a study undertaken in Nigeria to determine the incidence of pes planus amongst males and females concluded that the ratio is 1:4 (Dare *et al.,* 2012).

2.3.4 Pathophysiology

Pes planus is a common foot disorder characterised by the flat-footedness due to loss of the medial longitudinal arch. Pes planus leads to overpronation of the subtalar joint (STJ). In weight-bearing position, pronation is produced by eversion of the calcaneus with simultaneous plantarflexion and adduction of the talus on the calcaneus. Pronation is considered abnormal when it occurs in positions when the foot should be supinating, including during midstance or propulsion (Ball & Afheldt., 2002).

The medial longitudinal arch (MLA) comprises the calcaneus, navicular, talus, cuneiforms, and first to third metatarsals. The spring ligament, deltoid ligament; posterior tibial tendon; plantar aponeurosis; and flexor hallucis longus and brevis muscles support the MLA (Palastanga & Soames., 2012). The plantar aponeurosis makes up a sizeable central component of the foot, and its role is to stabilise the medial longitudinal arch and the first metatarsophalangeal joint (Hayes and Barbaro-Brown., 2017). Bartold (2017) mentions that the foot arch is heavily reliant on adjacent soft tissues to maintain its arch position and further states that the plantar fascia acts as a mechanical truss maintaining the integrity of the medial longitudinal arch. Dysfunction of any segment of the medial longitudinal arch may result in pes planus deformity (Raj *et a*l., 2019).

2.3.5 The pathomechanical implications of Pes Planus

There are various kinetic and kinematic changes seen in flat feet when compared to standard feet. The literature describes the following pathomechanic alterations as a result of flat feet: increased hindfoot eversion; increased forefoot plantarflexion and

abduction; reduced forefoot adduction, increased internal tibial rotation, and marked subtalar joint eversion (Kodithuwakku Arachchige *et al.,* 2019). These altered movement patterns affect normal gait and balance while predisposing the risk of injury. Malalignment of the foot can cause weakening of intrinsic muscles leading to musculoskeletal dysfunction and overuse injuries (Kodithuwakku Arachchige *et al.,* 2019). Flat feet may cause poor balance, muscle fatigue, cramping, pain, altered plantar pressure distribution and is often co-existent with rheumatoid arthritis (Kodithuwakku Arachchige *et al.,* 2019).

2.4 Clinical Assessment of Pes planus

To adequately manage pes planus, a correct diagnosis is necessary, and such a diagnosis should indicate the severity of the deformity as well. There are various assessment techniques used to assess foot type. These assessment methods vary from a simple visual examination to sophisticated techniques utilising technology. This section will provide a summary of the different methods employed to assess pes planus.

2.4.1 The Foot Posture Index® (FPI)

The FPI is a diagnostic tool aimed at quantifying the degree to which a foot can be considered to be in a pronated, supinated or neutral position. It is intended to be a simple method of scoring the various features of foot posture into a single quantifiable result, which in turn indicates the overall foot posture (Redmond, 2005). The FPI is a visual assessment of the foot by observing six clinical criteria of the foot while the patient is weight-bearing.

Redmond (2005) describes six clinical criteria employed in the FPI-6 as:

1. Talar head palpation
2. Supra and infra lateral malleolar curvature
3. Calcaneal frontal plane position
4. Prominence in the region of the talonavicular joint
5. Congruence of the medial longitudinal arch
6. Abduction/adduction of the forefoot to the rear foot

The Foot Posture Index© scoring criteria involves grading in which each component of the six clinical criteria tests/observations are simply graded 0 (zero) for neutral, with a minimum score of -2 for clear signs of supination, and +2 for positive signs of pronation commonly seen in a pes planus foot type (Redmond., 2005).

2.4.2 Tiptoe-standing test

In this clinical test, the patient is in a weight-bearing position and is required to stand on their toes. A clinician can confirm that a functional/flexible pes planus deformity exists if there is a clinical observation of a rise in medial longitudinal arch height (Merriman & Yates., 2009).

2.4.3 Navicular Drop Test (N.D)

In this study, the Navicular Drop (N.D) test was chosen to quantify the amount of pronation seen in pes planus deformity as lowering of the arch is associated with pronation (Christensen, Pedersen, Bengtsen, Andersen, Kappel & Rathleff., 2013). N.D, first described by Brody (1982), indicates that the purpose of the test is to assess the height of the navicular bone relative to the ground. Firstly, the height of the navicular bone is measured with the subtalar joint in the neutral position and then re-measured without the feet being in a neutral position. The difference between the first and second measurement is the navicular drop, measured in millimeters (mm).

Brody (1982) describes an N.D test value higher than 10mm as abnormal and indicates excessive foot pronation, and N.D values below 10mm are typical. A recent study undertaken by Umesh, Watson, Ganesh, and Joseph (2014) to determine normative values of N.D test has supported Brody's borderline values.

2.4.4 Radiological evaluation

Observation of a plain X-ray view of the foot may be used to assess pes planus. A lateral view (weight-bearing) is utilised to examine the medial column of the foot, with a pronated foot type, the talus is displaced medially and plantarly; the cyma line has a marked break, and the calcaneal inclination angle is low (between 0-10 degrees) (Merriman & Yates.,2009). The findings from X-ray assessments are frequently used to validate the measurements gathered from visual assessments. In most cases, soft tissue overlying the foot's skeletal structure might confound the interpretation of the clinical techniques. Thus, radiographic techniques are considered the gold standard

for assessing the foot's skeletal alignment in a static weight-bearing position. Therefore, angular foot measurements derived from x-rays are often used to validate clinical measures of foot posture. However, radiation exposure, accessibility, and high costs are some limitations associated with this type of evaluation (Kodithuwakku Arachchige *et al.,* 2019).

2.4.5 Arch Height Index (AHI)

Calculation of arch height may be performed using callipers, a measuring tape, a ruler, or specially designed devices such as arch-height-index measurement systems (AHIMS); footprints; force plates; or digital plantar foot photographs (Kodithuwakku Arachchige *et al.,* 2019). The mentioned tools are utilised to obtain a vertical measurement at the highest point of the medial longitudinal arch (MLA) in a sagittal plane. The assessment could be done in both weight-bearing or non-weight-bearing position (Kodithuwakku Arachchige *et al.,* 2019).

2.4.6 Foot Prints

Visual footprint assessment involves analysing a simple ink print of the foot on the paper. The imprint captured by the plantar surface of the foot is considered to reflect the magnitude of the MLA (Kodithuwakku Arachchige *et al.,* 2019). Footprints are a traditional method of assessing pes planus and are convenient, cost-effective, non-invasive, and do not require specialised devices nor technology (Kodithuwakku Arachchige *et al.,* 2019).

2.4.7 Three Dimensional (3D) Scanning

Cameras synchronised with 3D motion capture analysis system detect trajectories of foot segments; this can be used to assess both foot type and foot dynamics. This technology is becoming highly popular due to its high reliability, accuracy, and precision (Kodithuwakku Arachchige *et al.,* 2019).

2.5. Management of functional pes planus

It is known that flat feet can affect balance, cause fatigue, leg and foot pain, and increase susceptibility to injuries; therefore, it should be adequately managed to improve the quality of life (Kodithuwakku Arachchige *et al.,* 2019).

2.5.1 Orthotic Therapy

A custom orthotic is a medical device that fits in a shoe. Orthotics can influence the foot's posture and the distribution of the forces the foot exerts during weight-bearing (Lochner et al., 2012). Orthotic Therapy is based on the understanding of normal and pathological functioning of the lower limbs. The development of biomechanical paradigms started from clinical observation, advancing with the complex kinematic and kinetic analysis. A reference point is the subtalar joint neutral paradigm by Merton Root (1977). Root created a unified reference system based on standard foot definition through a set of eight criteria of normalcy (Daniel & Colda., 2012). Once the criteria of normalcy are established, any deviation from these criteria would indicate the presence of pathology (Daniel et al., 2012). Podiatrists widely accept custom foot orthotics produced with such a paradigm as beneficial devices in the treatment of foot pathologies that are often biomechanical (Lochner et al., 2012).

Custom foot orthoses are currently recognised as the gold standard amongst various treatment options available in the treatment of pes planus (Dombroski et al., 2014). Currently, South African podiatrists prescribe handmade orthotics for the management of pes planus; however, CAD/CAM orthoses are now prescribed by a limited number of podiatrists mainly due to cost implications.

As alluded to, podiatrists use orthotic devices in the management of functional pes planus. They use these devices to realign, stabilise, and provide support throughout the forefoot, midfoot, and hindfoot in pes planus feet. According to Chen *et al.* (2010), orthotics manufactured for pes planus are designed to provide stability and realignment of the medial longitudinal arch. In turn, orthotics can limit the amount of pronation in people with pes planus (Christensen et al., 2013). Figure 2 illustrates the effect of orthotic devices in controlling the amount of pronation in people with functional or flexible pes planus.

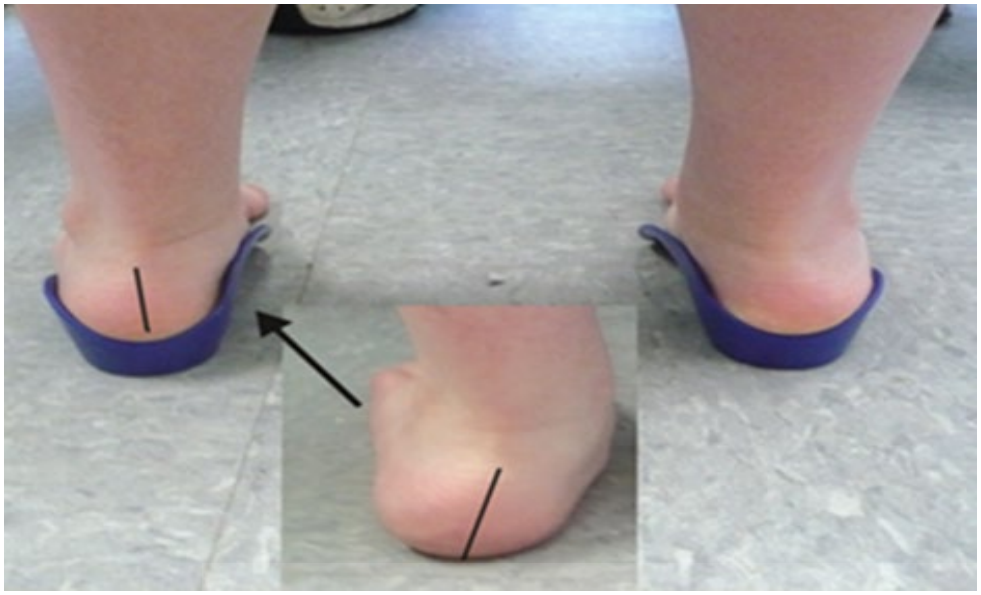

Figure 2 Realignment of functional pes planus deformity with an orthotic device (Merriman & Yates,2009).

Studies have shown orthotics' ability to control the amount of navicular drop in patients with pes planus. A study done by Christensen et al. (2013) found a reduction in N.D when wearing these orthotics. On average, these orthotics reduced the N.D by 0.4mm compared to the average N.D without orthotics (Christensen et al., 2013).

Another study by Ki, Leung & Li (2008) was undertaken on a Chinese population to compare plantar pressure distribution patterns between foot orthoses generated by the CAD/CAM and traditional methods. The results showed that foot orthoses generated by CAD/CAM system provided a pressure distribution pattern similar to those made by the conventional method, except the mid forefoot region where peak pressure was found to be lower in the CAD/CAM approach. In addition, D'Aminco, Roncoletta, Vermigili, and Gnaldi (2015) conducted a pilot study to define a protocol for the off-loading performances and statistical comparison of traditional and CAD/CAM designed foot orthoses in the diabetic foot. Their study found significant statistical improvement in the reduction of pressure by both orthoses. However, their comparisons confirmed that CAD/CAM orthoses achieve better performance than traditional ones.

Various studies conducted abroad regarding the use of orthotics for flexible pes planus deformity indicate positive results. In support of this, Kido et al. (2014) proved that there were positive structural changes in the alignment in the bones of the feet achieved by custom orthotics for individuals that present with flexible pes planus. Another study by Sheykhi-Dolagh et al. (2015) investigated the influence of foot orthoses on foot mobility magnitude and arch height index in individuals with flexible flat feet; this study found that orthotics brought arch height index close to normal arch height index when compared to barefoot alone. A review article by Douglas (2015) supports the use of orthotic treatment for the adult acquired flat foot, as it can be a powerful tool to correct alignment and prevent subluxation of the adult acquired flat foot. These studies confirmed that some parameters, such as alignment and arch height, were improved by orthotics amongst individuals presenting with flexible flat feet deformity.

Anecdotal evidence suggests that most practising podiatrists in SA are prescribing and manufacturing traditional handmade orthotics as compared to CAD/CAM orthotics for pes planus deformity. This technology remains costly in RSA, possibly due to the limited number of local suppliers as most suppliers are abroad. Therefore, an essential drawback of CAD/CAM systems is that they are generally expensive, making them out of reach for most podiatrists.

Foot orthoses are commonly used in the management of numerous lower limb pathologies, and various studies that report their positive effects have been done abroad. There is a significant gap in South African literature regarding the use, effectiveness, and variations between handmade and CAD/CAM orthoses. Thus, there is a need to explore any variations that may exist between handmade and CAD/CAM orthoses in South Africa.

2.5.2 Custom Foot Orthoses

2.5.2.1 Traditional handmade custom foot orthotics

This conventional approach, widely used among podiatrists, is wholly based on manual activities and craft-based processes that depend on individual podiatrists' skills and expertise that need considerable training skills and practise to reach optimal results (Fantini *et al.*, 2017). This type of method is one that has the most

prolonged existence amongst all other types of methods. Many podiatrists in RSA still utilise this traditional method in which custom foot orthoses are handmade. Firstly, a mould of the patients' foot is needed; these moulds can either be obtained by casting the patients' foot with Plaster of Paris bandage or by having the patient step into a box of compressible foam.

Once the casts are obtained, these serve as foot models to which a pair of custom orthotics will be manufactured. The foot models will then be corrected to a neutral position in which the heel and forefoot are perpendicular to the ground. This correction of the foot models may be time-consuming depending on the original shape of the foot model, creating an arch on the foot model where a flat foot exists. Correction of the foot model involves adding or removing Plaster of Paris to or from the foot model. Moreover, this approach is also unpleasant for patients during the cast impression and frequently needs to repeat the process if the orthotics have a poor fit on the patients' foot, resulting in time-consuming and material wasting (Fantini *et al.,* 2017). In support of this, Gatt et al. (2016) mention that fabricating custom orthoses manually is time-consuming and requires significant technical ability, thus creating the risk of error.

Figure 3 Traditional handmade custom foot orthotics manufacture process (Merriman & Yates.,2009).

2.5.2.2 Computer-Aided Design/ Manufactured foot orthoses (CAD/CAM orthoses)

Literature describes CAD/CAM orthoses as an advanced method of manufacturing custom foot orthoses. The first CAD/CAM system for orthoses production was the Orthocan system and was introduced in 1988 by American Digital Technology (Ki *et al*., 2008). However, this type of technology is still presently expensive and thus not available to the majority of podiatrists to consider as part of their routine clinical service, even though this technology offers various advantages over traditional methods (Gatt *et al*., 2016). Some advantages include accuracy, increased quality, a less messy process, and most importantly, providing faster turnaround time, benefitting the patient (Gatt *et al*., 2016).

In this novel approach, a three-dimensional laser scanner is used to capture a foot model. The podiatrist then designs the orthotics using CAD software, and each patient's design takes approximately fifteen minutes, ensuring a complete match to the patients' foot. Once this is complete, the scan is sent with all custom measurements and is ready to be fabricated by a CAM milling machine. The materials utilised to manufacture CAD/CAM orthoses such as ethylene-vinyl acetate and polyurethane are distinctively different from those employed by traditional methods (Gatt *et al*., 2016). This digital process minimises the time needed to obtain a foot model compared to conventional methods and limits correction errors (Fantini *et al.,* 2017).

Figure 4 Computer-Aided Design (CAD) orthotic manufacture process. (Gatt et al., 2016)

2.6 Summary

This chapter presented literature discussing functional pes planus, clinical assessment methods, and Orthotic Therapy with emphasis on the use of Handmade versus Computer-aided orthotics in the management of functional pes planus. Although anecdotal evidence suggests that most South African podiatrists prescribe handmade orthotics for the management of functional pes planus, there have not been studies done in South Africa to prove this; therefore, the literature review has highlighted various studies undertaken abroad. A more detailed description and defence of the study design and methodology is presented in the following chapter.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 INTRODUCTION

This study aimed to investigate, document, and compare handmade and CAD/CAM orthotics with regard to the effectiveness in the realignment of functional pes planus deformity. In this chapter, the research design and methodology are discussed, together with the ethical considerations applicable to the study.

3.2 RESEARCH DESIGN

Allen (2017) defines research design as a plan for a study, providing the overall framework for collecting data and further indicates that a sound research design aims to provide results that are judged to be credible. To meet the purpose and objectives of this study, a cross-sectional, descriptive quantitative method design was chosen for this study. A cross-sectional research design is described as one in which data is collected from a population at a given time (Cummings, 2018). This study was cross-sectional as it investigated and documented any significant differences that exist between handmade and CAD/CAM orthotics in the realignment of functional pes planus deformity.

Creswell (2018) mentions that quantitative research best attempts to test objective theories by examining the relationship among variables; these variables can be measured so that numbered data can be analysed using statistical procedures. This method was chosen to achieve the study's overall aim, which was to investigate, document, and compare handmade and CAD/CAM orthotics with regard to the effectiveness in the realignment of functional pes planus deformity.

This study was also descriptive in nature as it sought to describe the similarities and or differences (Creswell, 2018) between CAD/CAM and handmade orthotics by comparing the realignment of functional pes planus deformity achieved using both manufacturing methods.

3.3 TARGET POPULATION AND SAMPLE

3.3.1. Target population

Daniel (2017) describes a target population as a set of elements to which a researcher desires to apply the findings of the study. This study's target population was participants diagnosed with functional pes planus deformity at the University of Johannesburg Podiatry Clinic.

3.3.2. Sample population

Sampling is described as a group of individuals who actually participate in the study (Daniel, 2017). This study's sample population was fifty consented participants with functional pes planus for whom orthotics were manufactured.

3.3.3. Sample size

The role of a power analysis is to determine for the researcher the sample size needed to maximize success in answering research questions and hypotheses (Wiedmaier, 2018). Hence, a power analysis was conducted by a statistician at STATKON to determine the statistical sample size applicable to the study, and it was concluded that a maximum of 50 pairs of orthotics produced by each method (Traditional and CAD/CAM) would be suitable.

3.4 DATA COLLECTION AND ORTHOTIC MANUFACTURING PROCEDURE

Potential participants were recruited from the University of Johannesburg Podiatry Clinic. Patients consulting the Podiatry Clinic who were diagnosed with functional pes planus deformity were invited to participate in the study. The researcher explained the purpose of the study by reading the information letter to the participant (Annexure D). The participant was then requested to sign the consent form (Annexure E) to conclude participation before any data collection proceedings.

Each consenting patient was then taken to the Gait Laboratory for data collection. Firstly, the Tiptoe test and Foot Posture index was conducted to confirm the diagnosis being functional pes planus. Thereafter, the Navicular drop test was conducted to document the amount of pronation/ foot malalignment present without any orthotic devices. Each participant was then taken to the Orthotic lab for casting;

a negative cast/ foot model was captured with plaster of Paris bandage as this is needed to manufacture a pair of handmade orthotics. The participant was then asked to stand on a Zebris 3D scanner, and foot scans were captured for the manufacturing of a pair of CAD/CAM orthotics.

A qualified podiatrist who had been practising for more than ten years and owned an orthotic lab had been given 50 pairs of negative casts in order to manufacture 50 pairs of handmade orthotics for this study. Ripple Effect ®, a company currently in SA that manufactures CAD/CAM orthotics, had manufactured 50 pairs of CAD/CAM orthotics. Once both handmade and CAD/CAM orthotics were manufactured, the participants were then called back to return for final measurements. The navicular drop test was then performed for each participant standing on their pair of handmade orthotics then again on their CAD/CAM orthotics pair. The entire data collection process took six months.

3.4.1 Pes Planus measurements

To confirm that the participant had pes planus, the Foot Posture Index© (FPI) by Remond (2005) was measured by the researcher. To ascertain that the pes planus is functional/flexible, the participant was asked to perform the Tiptoe-standing test (Merriman & Yates, 2009). To quantify the amount of pronation associated with pes planus deformity, the Navicular Drop (N.D) test, first described by Brody (1982), was undertaken for each participant. As Christensen *et al.* (2014) state, lowering the arch is associated with pronation; the degree of pes planus was measured in millimeters (mm). All measurements captured were undertaken using validated tools, and data was captured on a data sheet (Annexure F) by the researcher.

3.4.2. Casting methods

There are different types of techniques that can be used to capture a foot impression. For purposes of the study, Plaster casting and 3D scanning were utilised to capture foot impressions for orthotics manufacture.

3.4.2.1. Plaster casting/ Negative casting

Described by Tunner & Merriman (2005) is a casting method in which plaster of paris bandages are used to capture a mould of a patients' foot; this is taken with the STJ

in neutral position hence it is called neutral impression cast (NIC) or a negative cast. The negative cast is then filled with plaster of paris resulting in a foot model from which handmade orthotics are manufactured.

Figure 4 Negative casting method (Tunner & Meriman, 2005).

3.4.2.2. Three dimensional (3D) scanning

This is an advanced method used to capture a foot impression, this Laser technology of casting is primarily used to manufacture CAD/CAM orthotics (Gatt et al., 2016). The Patient is semi weight-bearing / full weight-bearing, and the feet are placed on a 3D scanner, which scans an image of the foot to produce a three-dimensional image of the foot; various variables are captured on the image, e.g., Arch height, pressure areas, forefoot width, rearfoot width, foot length (Gatt et al., 2016).

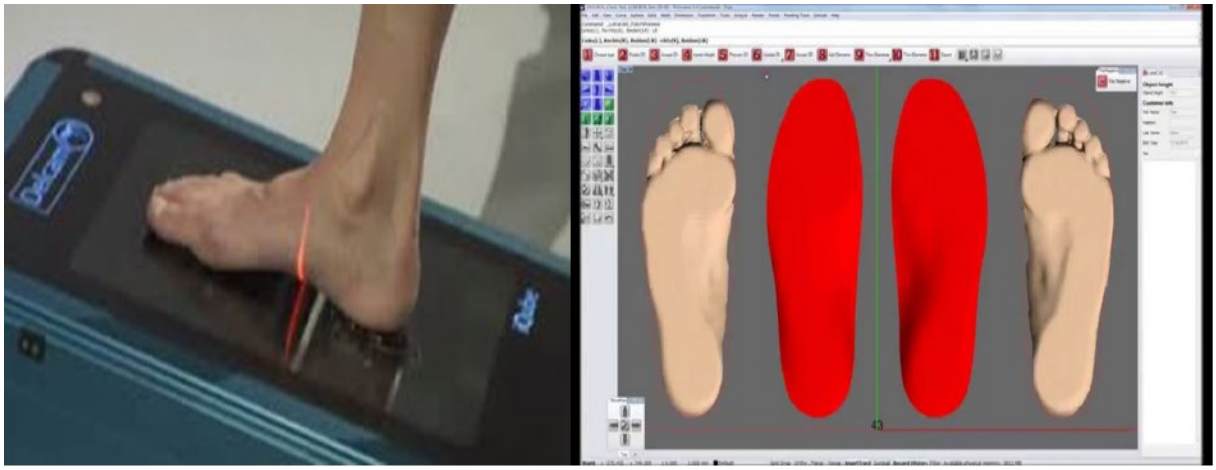

Figure 5 Three-dimensional (3D) scanning method (Gatt et al., 2016).

3.4.3. Manufacturing methods

A qualified podiatrist who owned an orthotic laboratory that manufactures handmade orthotics was tasked to manufacture all the handmade orthotics for the study. This podiatrist's laboratory has been manufacturing handmade orthotics for over ten years. All CAD/CAM orthotics were manufactured by Ripple Effect ®, an independent company that manufactures CAD/CAM orthotics as well as sell CAD/CAM software and hardware systems in South Africa. Orthotics manufactured were labelled in alphabetical pairs; for example, participant one had a pair labelled A1 and B1. In each pair, alphabetically belonging to each manufacturing method, pair A is traditionally handmade, and pair B produced by CAD/CAM system.

To measure significant differences between handmade versus CAD orthotics, the degree of realignment of functional pes planus was measured by using the N.D test in millimeters (mm) (Brody (1982). Thus, two measurements in total were taken for each participant, that is, one measurement with participants wearing a handmade orthotic and one measurement with participants wearing a CAD orthotic.

3.5 DATA ANALYSIS

Data analysis refers to the processes associated with surfacing meaning and understanding from the various data sets that may be collected during the research project as a basis for further action and theory building (Coghlan et al., 2014). The data analysed in this study consisted of measurements in millimeters to capture the degree of realignment of pes planus using the N.D test. Data was analysed using

Paired t-Test, Wilcoxon, and Friedman Test, as these tests were best suited for the measurable data in the study (STATKON, 2017).

3.5.1 Paired t-Test

This test is used when you have one group of people, and you collect data from them on two occasions or under two different conditions (SSPS, 2018).

3.5.2 Wilcoxon test

Also known as the Wilcoxon matched-pairs ranked test, this test is designed to use repeated measures, that is, when your subjects are measured on two occasions or under two different occasions. This test is also used to test significance (SSPS, 2018).

3.5.3 Friedman Test

It is a non-parametric alternative to the one-way repeated measured analysis of variance. It is used when you take the same sample of subjects or cases, and you measure them at three or more points in time or under three different conditions (SSPS, 2018).

The results are presented using graphs, tables, and pie charts in the Chapter that follows.

3.6 VALIDITY AND RELIABILITY

Validity and reliability techniques are focused on ensuring that the findings of a study are sufficiently accurate, believable, credible, and authentic (Ruel et al., 2018). Validity asks, “Is this measurement truly representative of the concept understudy?” Reliability asks, “If we repeat this measurement multiple times, will we obtain consistent results?” Both are necessary to classify a measurement as sound, accurate, relevant, and free of bias (Ruel et al., 2018). To achieve reliability, a measurement must be dependable, replicable, and consistent to minimize random error (Ruel et al., 2018). Validity and reliability were addressed in this study by applying scientifically validated clinical procedures and tests as described below.

3.6.1 Navicular Drop Test (N.D)

The Navicular Drop Test (N.D) is a simple and reliable measure of foot posture, which is more susceptible to detect arch height differences. Billis, Katsakiori, Kapodistrias, and Kapreli (2007) attribute good intra-tester reliability to N.D (Brody, 1982). Several authors provide evidence on high intra-tester reliability. In a study by Christensen *et al.* (2014) to investigate the validity of a novel method compared to the navicular drop test, it was found that there was concurrent validity compared to the navicular drop test by Brody (1982). N.D, first described by Brody (1982), indicates that the purpose of the test is to assess the height of the navicular bone relative to the ground. Firstly, the height of the navicular bone is measured with the subtalar joint in the neutral position and then re-measured without the feet being in a neutral position. The difference between the first and second measurement is the navicular drop, measured in millimeters (mm). Both measurements are captured using a ruler and recorded on cardboard paper.

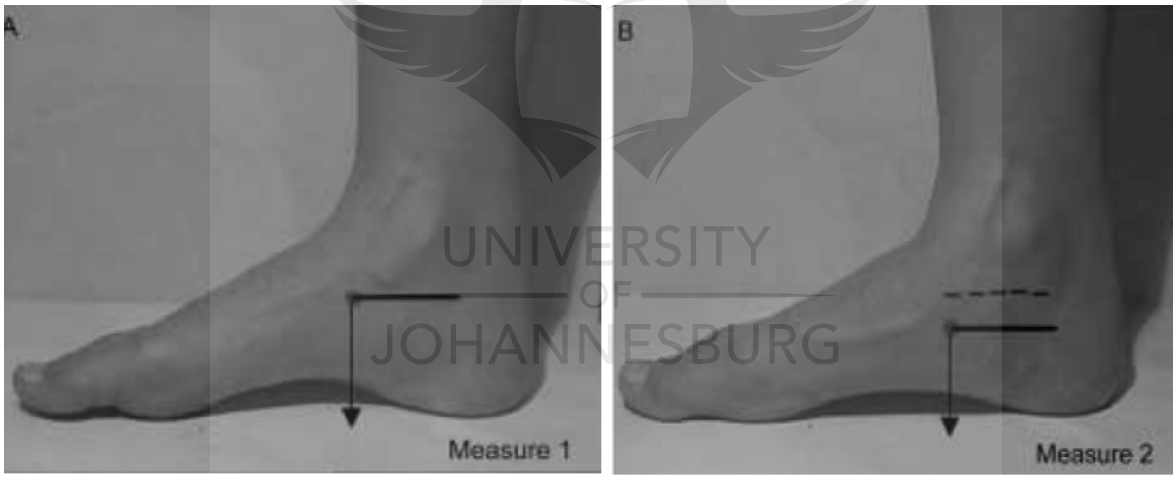

Figure 6 Navicular Drop Test (Billis et al, 2007).

4. ETHICAL CONSIDERATIONS

4.1 Permission to Conduct the Study

The Research Ethics Committee (REC) of the Faculty of Health Science, University of Johannesburg, granted ethical clearance (REC-241112-035). A permission letter (Annexure C) was sent to the Podiatry Clinic Manager requesting permission to recruit participants from the University of Johannesburg Podiatry Clinic for purposes

of this study. The core ethical considerations applicable to this study are discussed below

4.2 Informed consent

Field-Springer (2018) mentions that it is an ethical principle and requirement that those participating in a research study have the right to know that they are being researched, being told fully about the purposes of the research and its potential risks and benefits and that they can withdraw their participation at any time.

An information letter (Annexure D) was given to all potential participants to explain the aim and objective of the study. If they had any questions and concerns, these were discussed at this stage. All potential participants were informed of their right to choose to either take part in the study or not. They were also informed of their right to withdraw during the study's data collection phase, without any prejudice in their care. Those who agreed to participate in the study were asked to sign a consent form (Annexure E) to indicate their informed consent.

4.3 Confidentiality, Anonymity, and Privacy

Confidentiality and anonymity are ethical practices designed to protect human subjects' privacy while collecting, analysing, and reporting data. Confidentiality refers to separating or modifying any personal, identifying information provided by participants from the data. By contrast, anonymity refers to collecting data without obtaining any personal, identifying information. Typically, anonymity is the procedure followed in quantitative studies, and confidentiality is maintained in qualitative studies. In both cases, the researcher gathers information from participants, and it is this information that becomes the data to be analysed (Coffelt., 2018).

To ensure that Confidentiality, Anonymity and Privacy was achieved in this study, the following measures were put in place:

. All hard copies of data were kept in a locked cabinet, and all electronic data kept in a password-protected file. Only the researcher and supervisors have access to the data.

. All participants were known to the researcher; however, anonymity was guaranteed by not capturing any person's identifying data (e.g., names, file numbers, etc.). The only demographics that were captured included gender, age and population group.

. The right to privacy was protected as all measurements alluded to earlier were undertaken at the Podiatry department Gait lab, and casting was done in the casting room at the time where there were no students in the lab.

Data collected in this study will be stored by the Podiatry department for three years and will subsequently be destroyed.

4.4 Risks and Benefits

Risk refers to situations in which there is some significant probability that there will be a harmful outcome, whereas; Benefit of research typically means desirable outcomes for subjects and the community, science, and society. Both are important because, without bearing them in mind, one cannot plan ethically responsible research or propose a worthwhile project (Sieber & Tolich., 2013). There were no perceived risks or benefits associated with participation in this study.

5. SUMMARY

In this chapter, the researcher described and defended the design, methods, and research procedures that were followed to achieve the study's aim and objectives. Chapter 4 will present the quantitative results of the study.

CHAPTER FOUR: RESULTS

4.1 Introduction

This study aimed to investigate, document, and compare handmade and CAD/CAM orthotics with regard to the effectiveness in the realignment of functional pes planus deformity. Data was gathered and analysed using Paired t-Test, Wilcoxon, and Friedman Test as these tests were best suited for the measurable data in the study (STATKON, 2017). This Chapter will present, describe and compare the results of the study, which had the following objectives:

- To compare the difference in navicular drop achieved between the two manufacturing methods;
- To compare navicular drop between left and right foot with and without orthotic intervention and
- To identify if differences in realignment are significant.

The results of this cross-sectional, descriptive design study include non-parametric statistics presented descriptively in the form of pie charts, graphs, and tables.

4.2 Demographic Data

The prevalence of flat foot is not well defined in South African literature; hence the researcher had collected demographical data in this study, which included age, gender and race.

4.2.1 Age

The findings on participant age spread in this study are presented in figure 7.

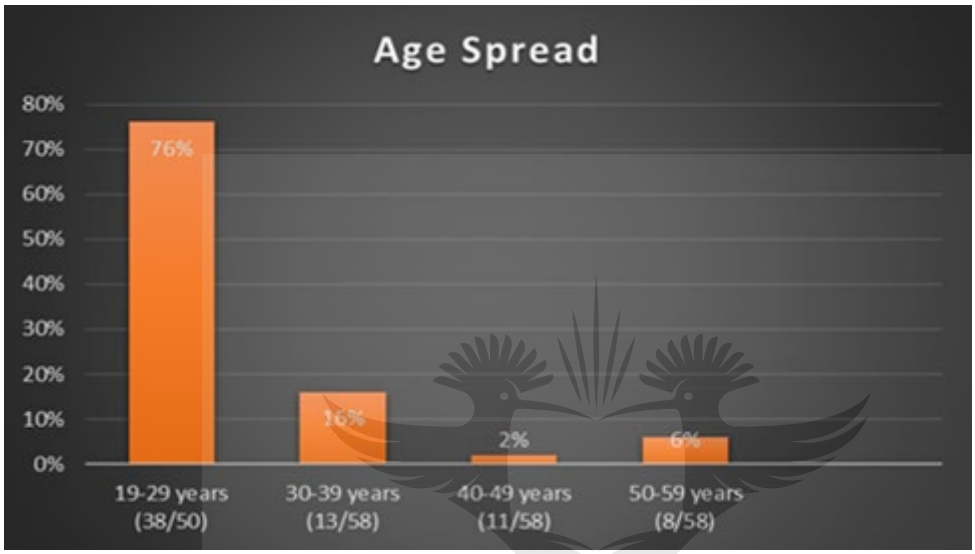

Figure 7 Age Spread

4.2.2 Gender

The participant gender distribution is presented in figure 8.

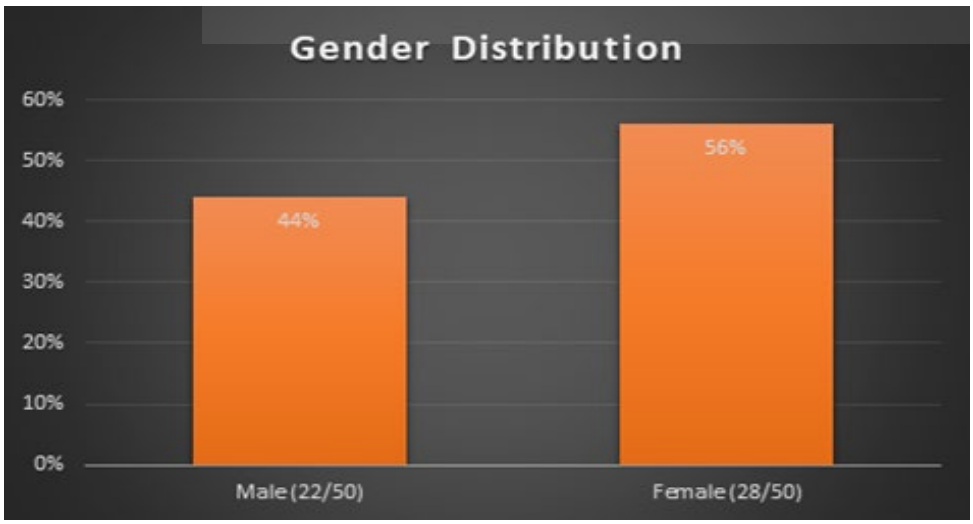

Figure 8 Gender distribution

4.2.3 Population group

The participant population group spread is presented in figure 9.

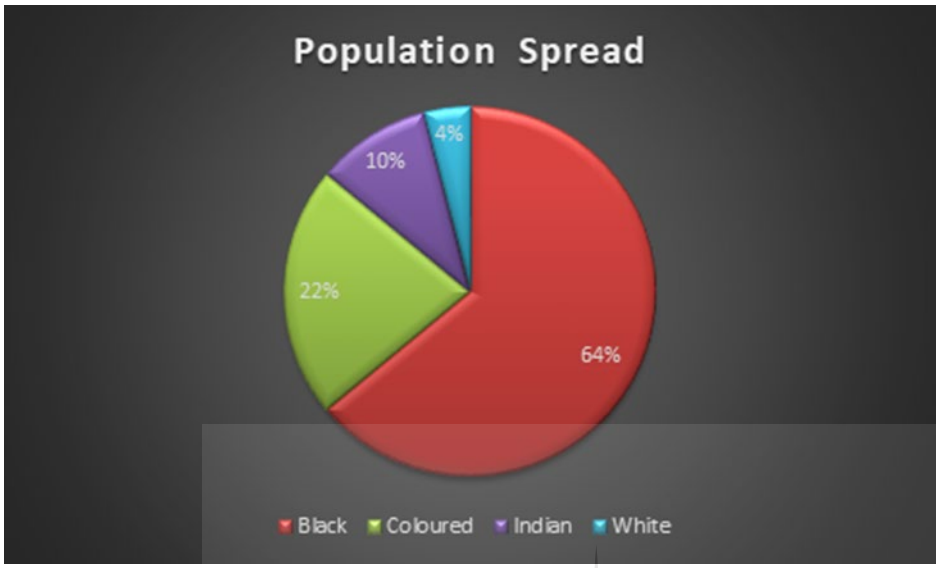

Figure 9 Population group Spread

4.3 Foot Posture Index (FPI)

The FPI is a diagnostic tool aimed at quantifying the degree to which a foot can be considered to be in a pronated, supinated or neutral position. It is intended to be a simple method of scoring the various features of foot posture into a single quantifiable result, which in turn indicates the overall foot posture (Redmond, 2005). The FPI is a visual assessment of the foot by observing six clinical criteria of the foot while the patient is weight-bearing.

4.3.1 FPI Right Foot

Figure 10 illustrates The Foot Posture Index amongst the participants' right foot.

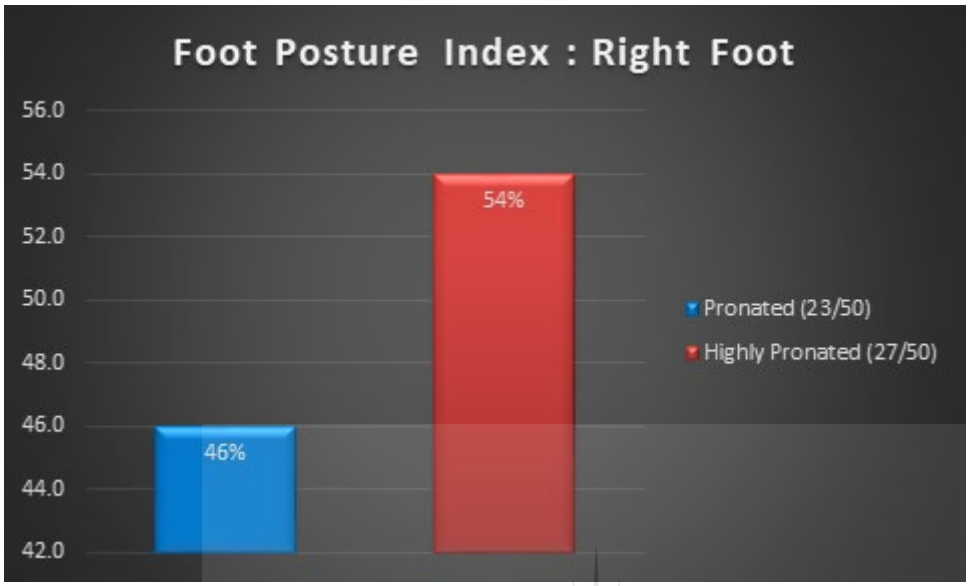

Figure 10 Foot Posture Index: Right foot

The Foot Posture Index of the Right foot presented above illustrates that 54% of the participants had a highly pronated index, and 46% had a pronated index.

4.3.2 FPI Left Foot

Figure 11 illustrates the Foot Posture Index of the participants' Left foot**.**

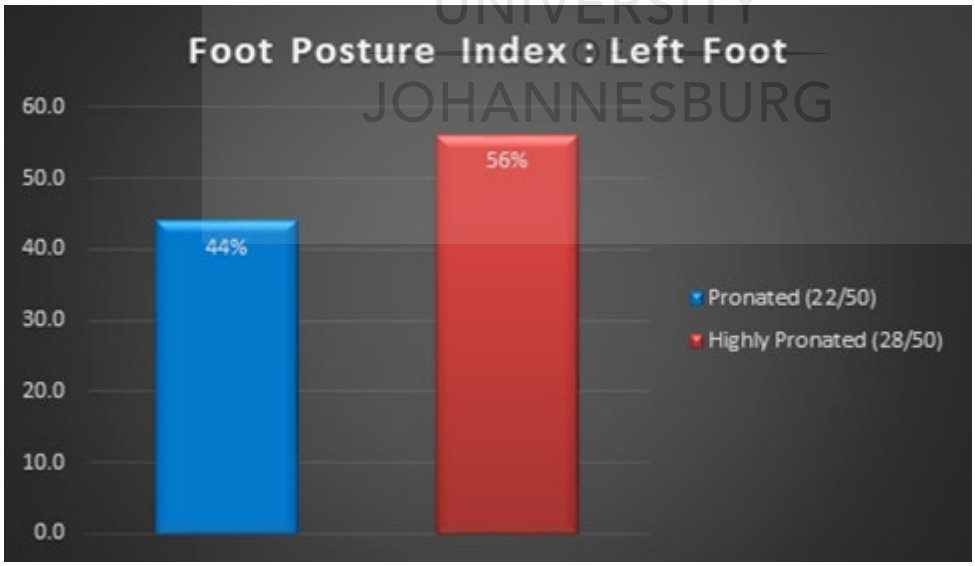

Figure 11 Foot Posture Index: Left foot

The Foot Posture Index of the Left foot presented above illustrates that 56% of the participants had a highly pronated index, and 44% had a pronated index

4.4 Standing Tiptoe Test

In this clinical test, the patient is in a weight-bearing position and is required to stand on their toes. A clinician can confirm that a functional/flexible pes planus deformity exists if there is a clinical observation of a rise in medial longitudinal arch height (Merriman & Yates., 2009).

The Standing Tiptoe Test is presented below in figure 12.

Figure 12 Standing Tip Toe Test

The Standing Tiptoe Test presented above illustrates that 100% of participants tested positive indicative of having flexible pes planus.

4.5 Navicular Drop (N.D) without orthotic devices

In this study, the Navicular Drop (N.D) test was chosen to quantify the amount of pronation seen in pes planus deformity as lowering of the arch is associated with pronation (Christensen et al., 2013). N.D, first described by Brody (1982), indicates that the purpose of the test is to assess the height of the navicular bone relative to the ground. Firstly, the height of the navicular bone is measured with the subtalar joint in the neutral position and then re-measured without the feet being in a neutral position. The difference between the first and second measurement is the navicular drop, measured in millimeters (mm). To evaluate the orthotics' effectiveness in this study, the researcher measured the navicular drop in all participants. The results in figure 13 are the measurements of navicular drop without any orthotic device.

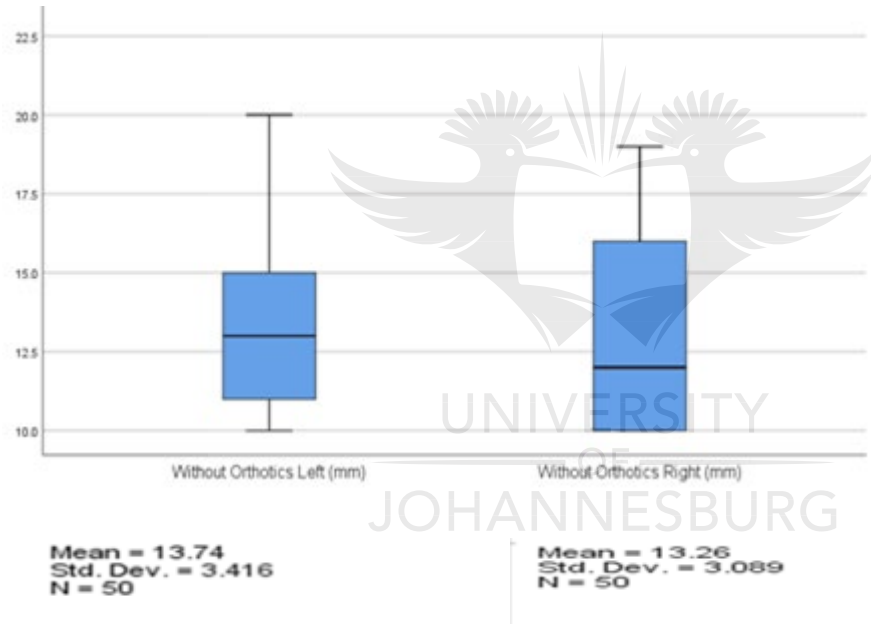

Figure 13 Navicular Drop (N.D) without orthotic devices

The Average Navicular drop measured in millimeters (mm) of the Right and Left foot presented above illustrates that the N.D median of the Right foot was 12mm and the Left foot being 13mm. Both feet were in excessively pronated limits with no significant statistical variation.

4.6 Navicular Drop (ND) with handmade orthotics

4.6.1 N.D with handmade orthotics Right foot

The results in figure 14 are the measurements of the navicular drop with handmade orthotic devices for the right foot.

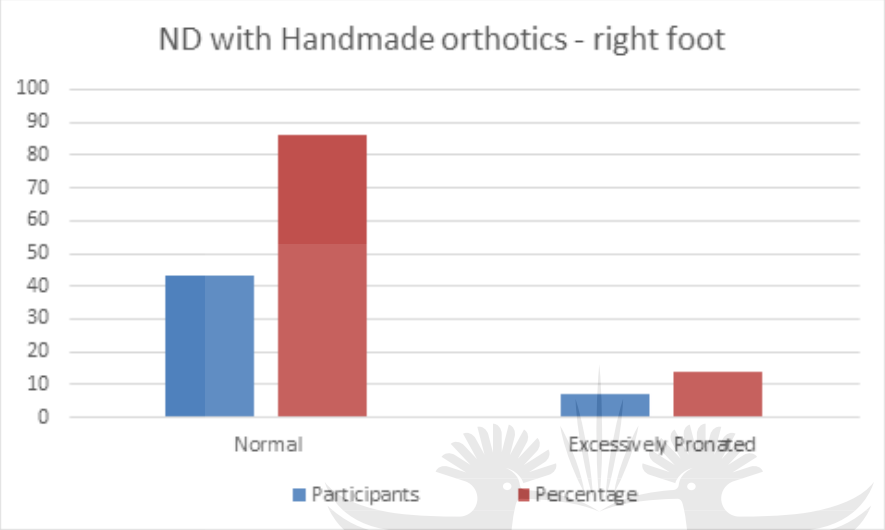

Figure 14 Navicular Drop (N.D) with handmade orthotics

The Navicular drop measured in millimeters (mm) of the Right foot presented in figure 8 above illustrates that the N.D was within normal limits amongst 86% (43/50) of participants and 14% (7/50) of participants were in excessively pronated limits (N.D greater than 10mm).

4.6.2 N.D with handmade orthotics Left foot

Figure 15 presents the findings of the Navicular drop measurements for handmade orthotics for the Left foot.

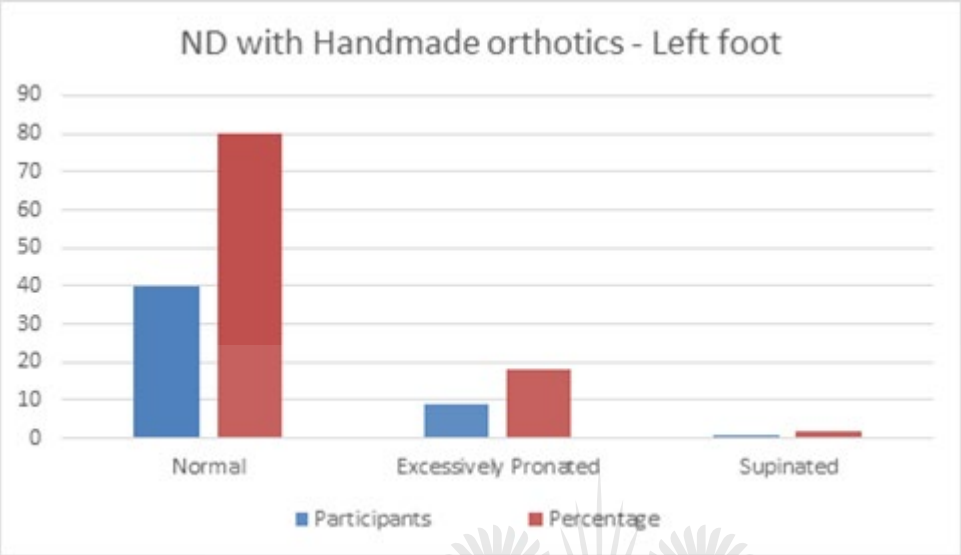

Figure 15 Navicular Drop (N.D) with handmade orthotics

The Navicular drop measured in millimeters (mm) of the Left foot presented above in figure 15 illustrates that the N.D was within normal limits (N.D less than 10mm) amongst 80% (40/50) of participants, 18% (9/50) of participants were in excessively pronated limits, and 2% (1/50) was in supinated limits.

4.7 Navicular Drop (N.D) with Computer-aided design/manufactured (CAD/CAM) orthotics

4.7.1 N.D with CAD/CAM orthotics Right foot

Figure 16 presents the findings of the Navicular drop measurements for CAD/CAM orthotics for the Right foot.

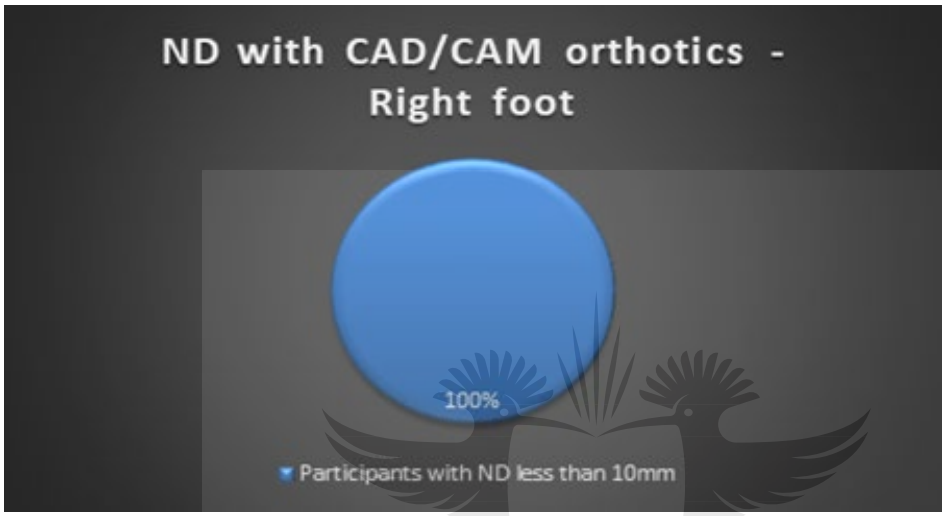

Figure 16 Navicular Drop (N.D) with CAD/CAM orthotics

The Navicular drop measured in millimeters (mm) of the Right foot presented in figure 16 above illustrates that the N.D was within normal limits amongst 100% (50/50) of participants.

4.7.2 N.D with CAD/CAM orthotics Left foot

Figure 17 presents the findings of the Navicular drop measurements for the Left foot.

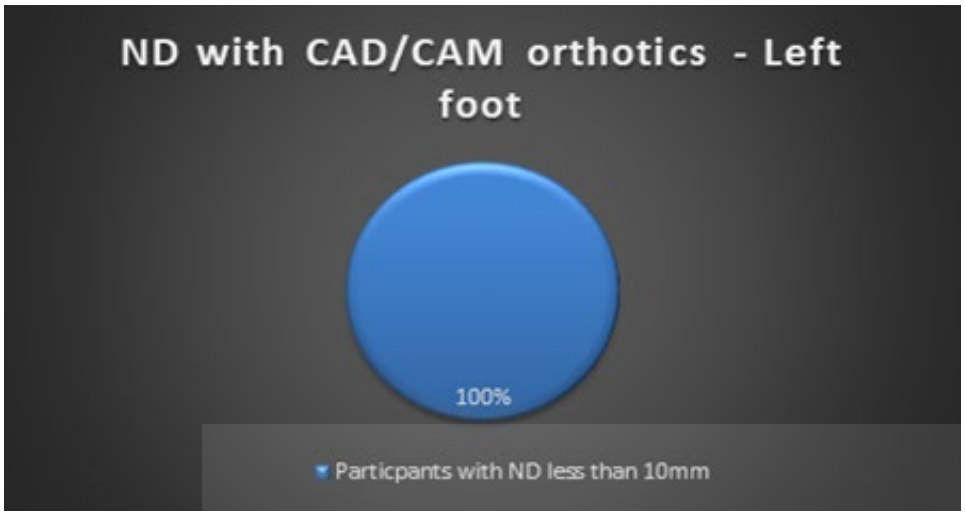

Figure 17 Navicular Drop (N.D) with CAD/CAM orthotics

The Navicular drop measured in millimeters (mm) of the Left foot presented in figure 17 above illustrates that the N.D was within normal limits amongst 100% (50/50) of participants.

4.8 Comparison of average Navicular Drop (N.D) between Handmade and CAD/CAM orthotics

Table 1 presents a statistical comparison of the Average Navicular drop measured in millimetres (mm) of the Right and Left foot.

Average Navicular Drop (N.D) measured in millimeters	Right foot N.D (mm)	Left foot N.D (mm)	Navicular drop reference values (Brody, 1982)
Without Orthotics	12mm	13mm	*Normal = 5mm to 9mm* *Excessively Pronated= ≥ 10mm* *Supinated= 0 to4mm*
With Handmade Orthotics	8mm	8mm	*Normal = 5mm to 9mm* *Excessively Pronated= ≥ 10mm* *Supinated= 0 to4mm*
With CAD/CAM Orthotics	6mm	6mm	*Normal = 5mm to 9mm* *Excessively Pronated= ≥ 10mm* *Supinated= 0 to4mm*

Table 1 Comparison of average Navicular Drop (N.D) between Handmade and CAD/CAM orthotics

The above table illustrates that an average N.D variation of 2mm exists between handmade and CAD/CAM orthotics, meaning an average of 2mm CAD/CAM orthotics achieved more realignment compared to handmade orthotics.

4.9 Summary

This Chapter has presented, described, and compared the results of the study, which had the following objectives:

- To compare the difference in navicular drop achieved between the two manufacturing methods;
- To compare navicular drop between left and right foot with and without orthotic intervention and;
- To identify if differences in realignment are significant.

In the following Chapter, the results presented above will be discussed in greater detail with regard to their relevance for current and future prescription and application of orthotics for the management of pes planus.

CHAPTER FIVE: DISCUSSION

5.1 Introduction

Pes planus is a common foot pathology also referred to as a flat foot. It is a postural appearance of the foot, with a collapsed medial longitudinal arch and a pronated subtalar joint (Dare et al., 2012). In support of this, Banwell (2015) states that pes planus is characterised by a loss of medial longitudinal arch height and is often associated with rearfoot eversion. Furthermore, pes planus leads to foot malalignment, instability of the medial foot structure, and an altered gait pattern (Chen et al., 2010). Malalignment of the foot can cause weakening of intrinsic muscles leading to musculoskeletal dysfunction and overuse injuries (Kodithuwakku Arachchige *et al.,* 2019). Flat feet may cause poor balance, muscle fatigue, cramping, pain, and altered plantar pressure distribution (Kodithuwakku Arachchige *et al.,* 2019).

Foot orthoses are the current gold standard amongst various treatment options available in the treatment of pes planus (Dombroski et al., 2014). In pes planus, foot orthoses provide comfort, reduce the frequency of movement-related injuries, align the skeleton, reduce muscle activity, and reduce joint movements. Thus, their function is to realign, stabilise, and provide support throughout the forefoot, midfoot, and hindfoot in pes planus feet. For many years, custom foot orthotics (CFOs) have been manufactured using Plaster of Paris casting or impression foam methods according to the practitioner's specifications. Manually fabricating custom orthoses is time-consuming and requires extensive technical ability. The process lends itself to a high risk of error and, as alluded to, is practitioner-reliant figure 18.

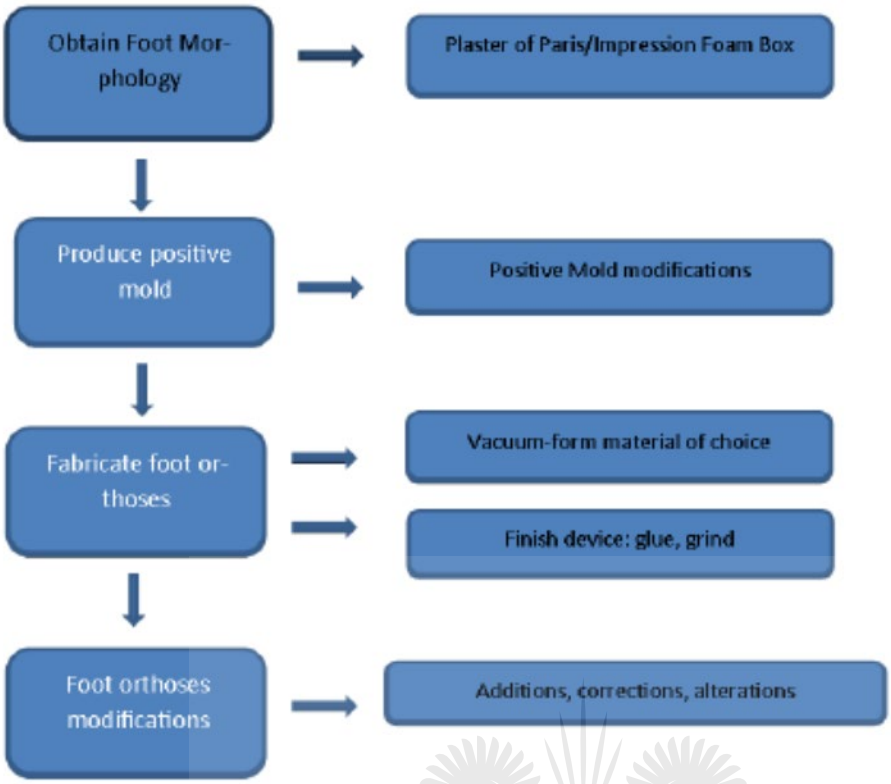

Figure18 The handmade orthotic manufacturing process (Gatt et al., 2016).

New, more advanced computerised methods of manufacturing foot orthoses have been developed over the years, utilising Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM) technology. Such systems often incorporate a 3D scanner, software, and milling machine. Compared with the traditional foot orthoses manufacturing process, the CAD/CAM process offers obvious advantages, including increased accuracy, reproducibility of the printed/milled devices, improved quality, and faster turnaround time benefiting the patient (Gatt et al., 2016).

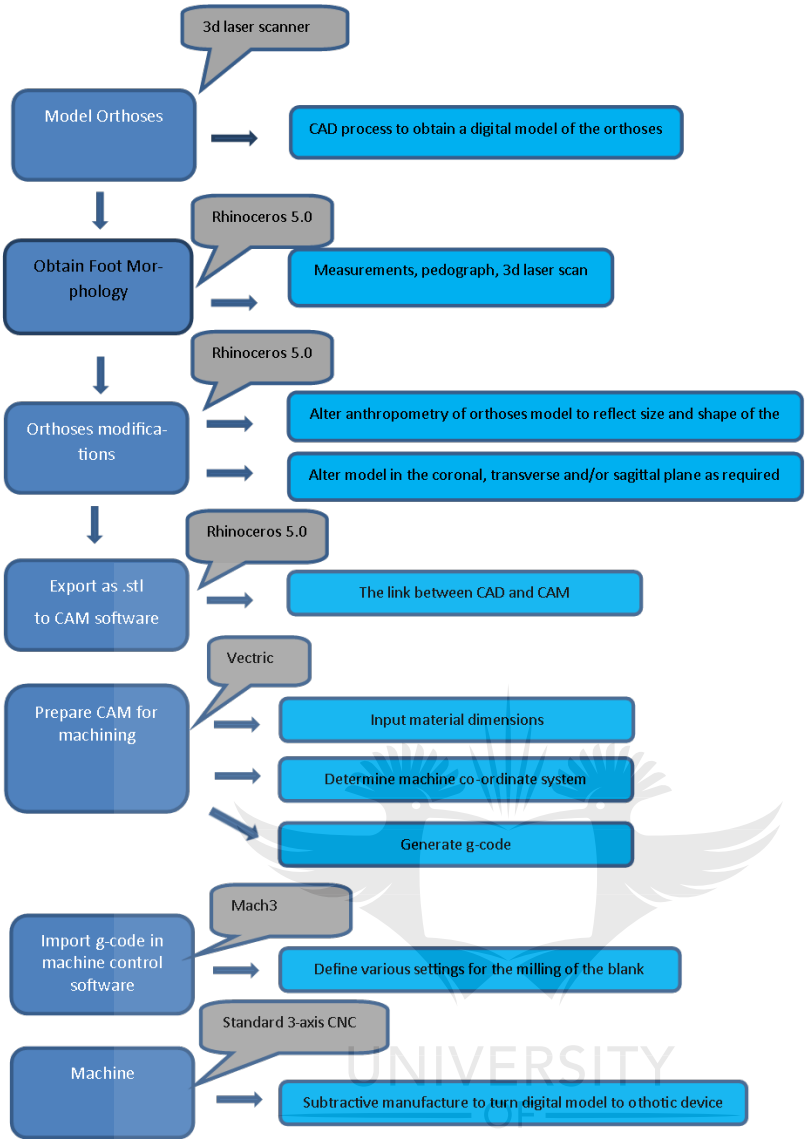

Figure 19 The CAD/CAM orthotic manufacturing process (Gatt et al., 2016).

According to Chen *et al.* (2010), orthotics manufactured for pes planus aim to provide the medial longitudinal arch's stability and realignment. In turn, orthotics can limit the amount of pronation and prevent associated foot-related complications (Christensen et al., 2013). However, anecdotally, handmade orthotics' criticism is the apparent ad hoc approach to these devices' manufacture options. This lack of evidence will be one of the fundamental issues confronting the podiatric profession in RSA. Currently, the government and other funding agencies are rapidly moving towards policies that support evidence-backed modalities. The podiatry profession will and is already struggling to motivate for orthotic use. Without evidence, medical aid coverage for orthotics, primarily for the more expensive orthoses, is challenged, and medical schemes' subsidy is reduced.

However, South African podiatrists prescribe handmade orthotics to manage pes planus despite the availability of advanced technology CAD/CAM orthotics. Literature describes the disadvantages of traditional handmade orthotics compared to CAD/CAM orthotics, yet to date, podiatrists still prescribe handmade orthotics. It remains unclear how the profession incorporates evidence-based medicine regarding the manufacture and use of orthotics. However, some factors may be driving the continued use of handmade CFOs in RSA.

These reasons could include the cost implications of CAD/CAM and limited undergraduate training, creating scepticism for using this technology. Despite the scepticism of CAD/CAM, these orthotics have achieved reliable status in the realignment of pes planus. Recent studies support the effectiveness of these devices. However, in RSA, the efficacy of handmade orthotics in the realignment of pes planus remains unknown and, in fact, under-researched. Thus this study aimed to investigate, document, and compare handmade and CAD/CAM orthotics concerning the effectiveness in the realignment of functional pes planus deformity.

The current study has shown limited efficacy of handmade orthotics when compared to CAD/CAM orthotics. These findings estimate CAD/CAM orthosis as reliable and have highlighted some concerns in handmade orthotics' efficacy. This chapter discusses the results of the study presented in the previous chapter. Where relevant and appropriate, the findings supported or contrasted with published literature.

5.2 Pes planus deformity and its management

Pes planus (flat foot) is an umbrella term to describe feet with a visually lowered medial longitudinal arch, often associated with rearfoot eversion (Shibuya, Jupiter, Ciliberti, VanBuren & La Fontaine, 2010:363-368). The World Health Organisation defines rigid pes planus as a congenital, rigid, or spastic deformity of the foot and flexible pes planus as an acquired joint disorder resulting in a valgus foot deformity (WHO: ICD-10 Diseases of the musculoskeletal system and connective tissue. Geneva: World Health Organisation; 2010). Pes planus presents in two forms, described as rigid or flexible (functional) (Luhmann, Rich & Schoenecker, 2000:59-66).

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Figure 20 Pes planus (O'Donelle,2010)

Functional pes planus is a foot deformity often presented to practising podiatrists. Functional pes planus reportedly affects between 2 and 23% of the U.S. adult population (Golightly, Hannan, Dufour & Jordan, 2012:1756-1759, Shibuya, Jupiter, Ciliberti, VanBuren & La Fontaine, 2010:363-368). No data indicates the prevalence of pes planus (rigid or functional) in RSA. Although well recognised within clinical practice and orthopedic literature, no universally accepted classification and standardised measure of flexible pes planus exist (Shibuya, Jupiter, Ciliberti, VanBuren & La Fontaine, 2010:363-368). In most cases, radiographic investigations are the reference standard to determine the magnitude of pes planus. However, it is measured clinically using a variety of static foot posture indices, each with its limitations (Butler, Hillstrom, Song, Richards & Davis, 2008:102-106, McPoil, Cornwall, Vicenzino, Teyhen, Molloy, Christie & Collins, 2008:220-227, Evans, Copper, Scharfbillig, Scutter & Williams, 2003:203-213).

The aetiology of functional pes planus remains unknown. Functional pes planus may be asymptomatic with little need for intervention or symptomatic with pain and/or functional limitations are present (Evans, 2009:179). The frequently reported signs include abnormal rearfoot kinematics (e.g., excessive rearfoot eversion or increased range of rearfoot eversion), abnormal foot and ankle kinetics (e.g., elevated joint movements or abnormal loading forces), and altered physical function (e.g., altered muscle activation and timing or increased energy consumption) (Banwell, Mackintosh & Thewlis, 2014:23). The symptoms of flexible pes planus are related to

the reported signs' functional consequences (Farmani, Sadeghi, Saeedi & Kamali, 2011:60-62), thus, the interventions in functional pes planus should address the foot function (Schuitema, Greve, Postema, Dekker & Hijmans, 2019:1-18, Hawke, Burns, Radford & du Toit, 2008:1-2).

In RSA, podiatrists frequently prescribe foot orthoses as an intervention for functional pes planus. The orthotic aims to influence the subtalar joint's position towards a neutral position and reduce abnormal motion around this joint. An orthosis is an in-shoe medical device that alters the reaction forces' magnitudes and temporal patterns, allowing for a more normal foot and lower extremity function that decreases pathological loading forces (Kirby, 1997). Based on these definitions, orthotic use to alter the signs of flexible pes planus and ameliorate symptoms is plausible.

Figure 21 Realignment of pes planus with and without orthotics (Frowen,2010).

The advent of CAD-CAM orthotics has enabled precision design devices when compared to hand made devices. However, there is no data to indicate the efficacy of either device in RSA. Currently, for the conservative management of pes planus CFOs are frequently prescribed. Within the podiatry domain, it is generally accepted that this therapeutic modality produces positive clinical outcomes. However, it remains unclear how this intervention influences the dynamics of the lower extremity, mainly as the measurements for CFOs are not as precise as in CAD/CAM orthotics.

Despite their widespread use, CFOs designed to limit the pronation of pes planus have not been shown to change the medial-lateral ground reaction forces significantly on the foot (Kodithuwakku, Chander & Knight, 2019:81-85, Farmani, Sadeghi, Saeedi & Kamali, 2011:60-62).

This study did not seek to establish the incidence of functional pes planus. However, age and gender factors were considered important demographic data regarding functional pes planus deformity. In this study, the participant age spread ranged between 19 - 59 years. The majority (76%) of the participants were between 19 and 29 years. These findings are in line with literature that mentions that functional pes planus may affect any age. This condition may be congenital or acquired, known to have a strong genetic component as it typically is familial (Dunn et al.,2004). The researcher could assume the young age spread shown in this study's results could belong to pes planus of a familial nature.

Concerning the gender spread in this study, most participants (56%) were female, and 44 % were male. A South African study conducted by Erasmus (2016) found that males had a higher incidence of flat feet. Literature suggests a 1:1 ratio of men to women. However, the current study was in line with Aenumulapalli's (2017) studies and Dare (2012) that have shown the incidence of pes planus being higher amongst females.

5.3 Diagnosis of pes planus deformity

Podiatrist plays a crucial role in the assessment, diagnosis and the management of pes planus deformity. The intervention pathways in pes planus remain predominantly unclear, undefined, and controversial. In most cases, interventions seek to address the associated symptoms. These symptoms may include generalised lower limb pain, increased lower limb fatigue, Achilles tendinopathy, osteoarthritis, patellofemoral disorders, and hip pain (Jung, Koh & Kwon, 2011:225-231). Although pes planus is well recognised within podiatric clinical practice and orthopedic literature, no universally accepted classification and standardised measure of functional pes planus exists. In RSA, there is not even a consensus on the use of orthotics in functional pes planus, unlike other countries like Australia and the United Kingdom (Banwell, Mackintosh, Thewlis & Landorf, 2014:49).

A typical lower extremity examination focuses on podiatric biomechanics. This biomechanical examination includes specific foot assessments that are essential to measure pes planus deformity's severity and reach a diagnosis. Once the severity of pes planus is ascertained, then can a podiatrist adequately manage pes planus. New podiatric biomechanics paradigms have emerged over the years to enhance clinical assessments and clinical interventions for pes planus (Kirby., 2006:36-48). In this study, the Foot Posture Index (FPI) and Navicular Drop test (N.D) were the two assessments utilised to measure the severity of pes planus among the participants, mainly to measure the amount of misalignment associated with pes planus.

5.3.1 Foot Posture Index (FPI)

The Foot Posture Index (FPI) is a diagnostic tool aimed at quantifying the degree to which a foot can be considered pronated, supinated, or neutral in position. It is a simple method of scoring the various foot posture features into a single quantifiable result, indicating the overall foot posture (Redmond, 2005). The Foot Posture Index© scoring criteria involves grading in which each component of the six clinical criteria tests/ observations is graded 0 (zero) for neutral, with a minimum score of -2 for clear signs of supination, and +2 for positive signs of pronation commonly seen in a pes planus foot type (Redmond., 2005). In this study, the researcher calculated the total FPI score for each participant and classified each foot based on reference values suggested by Remond (2005). A "normal" foot is between zero and +5; "pronated" foot would be between +6 to +9, and a "highly pronated" foot would be +10 and above (Redmond, 2005).

This study found that 54% (27/50) of the participants had a highly pronated index, and 46% (23/50) had a pronated index of the right foot. In contrast, the left foot was at 56% (28/50) of a highly pronated index and 44% (22/50) being a pronated index. This meant that the participants had total FPI values between +6 to +10, rendering pronated or highly pronated feet. These findings are supported by a study undertaken by Kuo & Liu (2017), which mentions that FPI may vary due to multiple factors such as age, weight, and high impact sport. In this study, the researcher could associate age as an influential factor for the variations in the participants' FPI values captured. In hindsight, it would have been interesting to record the

participants' weight and sporting activities in this study to see if these factors influenced foot posture.

5.3.2 Navicular Drop Test

In this study, the Navicular Drop (N.D) test was chosen to quantify the amount of pronation seen in pes planus deformity. The lowering of the arch is associated with pronation (Christensen et al., 2013). N.D., first described by Brody (1982), indicates the purpose of the test is to assess the height of the navicular bone relative to the ground. Brody (1982) describes an N.D value greater than 10mm as abnormal and is indicative of excessive foot pronation, and N.D values below 10mm are seen as normal. A recent study undertaken by Umesh et al. (2014) to determine the N.D test's normative values has supported Brody's borderline values.

Billis et al. (2006) attribute good intra-tester reliability to N.D (Brody, 1982). He considers N.D a simple and reliable measure of foot posture, which is more susceptible to detect arch height differences. Several authors provide evidence on high intra-tester reliability. In a study by Christensen *et al.* (2014) to investigate the validity of a novel method compared to the navicular drop test, it was found that there was concurrent validity compared to the navicular drop test by Brody (1982). In this study, the total N.D was measured for each participant and classified based on reference values suggested by Brody (1982) as "normal" between 5mm and 9mm; "excessively pronated" greater than 10 mm, and "supinated" between zero and 4mm.

Initially, all participants' N.D values were measured to capture the severity of foot malalignment without the use of orthotics. This study found the Average N.D median of the Right foot at 12mm and the Left foot being 13mm. Both feet were in excessively pronated limits with no significant statistical variation. Since the participants' feet were excessively pronated, it was expected that N.D would be brought to normal limits by foot orthotics as realignment is the primary function of orthotics.

Another important role that podiatrists play in the management of pes planus would be the manufacture of custom foot orthotics. A custom orthotic is a medical device that fits in a shoe. Orthotics can influence the foot's posture as well as the distribution of the forces the foot exerts during weight-bearing (Lochner et al., 2012).

With reference to pes planus, podiatrists manufacture custom foot orthotics primarily to realign the foot as a treatment intervention. This is important because podiatrists assess the mal-alignment of pes planus prior to orthotic manufacture; they never assess the amount of realignment achieved by the orthotic device manufactured for the patient. Thus, there was an urgent need to investigate the efficacy of these custom made orthotics manufactured by podiatrists.

5.4. Traditional handmade custom foot orthotics

Pes planus can affect balance; cause fatigue, leg and foot pain, and increase susceptibility to injuries. Therefore, pes planus should be adequately managed to improve life quality (Kodithuwakku Arachchige *et al.,* 2019). Currently, South African podiatrists traditionally prescribe handmade orthotics for the management of pes planus. As alluded to, podiatrists use orthotic devices in the management of functional pes planus. They use these devices to realign, stabilise, and provide support throughout the forefoot, midfoot, and hindfoot in pes planus feet. According to Chen *et al.* (2010), orthotics manufactured for pes planus are designed to provide the medial longitudinal arch's stability and realignment. In turn, orthotics can limit the amount of pronation in people with pes planus (Christensen et al., 2013).

Traditional handmade custom foot orthotics is a conventional approach, widely used among podiatrists, is wholly based on manual activities and craft-based processes that depend on individual podiatrists' skills and expertise that need considerable training skills and practise to reach optimal results (Fantini *et al.*, 2017). This type of method is one that has the most prolonged existence amongst all other types of methods. The method is based on Root's approach. Clinicians conduct non–weight-bearing assessments of a patient's subtalar joint with the purpose of finding its neutral position (Root, Orien & Weed, 1977:358-370). Hence, the foot's pathologic condition and the patient's need for an orthotic is assessed from this starting position. With the foot held in the subtalar neutral position, a plaster cast could be made of the foot's shape; then, an orthotic device could be fabricated from rigid or semi-rigid materials based on impressions made in the cast.

Many Podiatrists in RSA still utilise this traditional method in which custom foot orthoses are handmade. This is even though the sub-talar neutral position's supposed importance has never been validated. Recent studies suggest that

orthoses based on the subtalar neutral approach inherently favour supination, despite this practise's "neutral" intent (Schuitema, Greve, Postema, Dekker & Hijmans, 2019:1-18, Banwell, Mackintosh & Thewlis, 2014:23, Ball and Afheldt, 2002:125-134).

This approach is also unpleasant for patients during the cast impression and produces orthotics that are not biomechanically sound. The process frequently needs repeating if the orthotics have a poor fit on the patients' foot, resulting in time-consuming and material wasting (Fantini *et al.,* 2017). In support of this, Gatt et al. (2016) mention that fabricating custom orthoses manually is time-consuming and requires significant technical ability, thus creating the risk of error.

In an economically challenging environment, this process may prove costly for both the patient and the treating podiatrist. Patients may have to visit the practitioner more than once for the measurements. This approach is unsustainable and does not make business sense, and flies in the face of evidence-based practise.

Even though literature describes these disadvantages of this ancient method of manufacturing orthotics, podiatrists in RSA still utilise this method, which is solely due to the undergraduate training of a podiatrist in RSA. In the undergraduate training of podiatrists in RSA, this orthotics manufacturing method is the only method taught. Throughout the four years of training, orthotic manufacture skills are progressively advanced. However, human error and inter or intra variations can never be eliminated. Once a student graduates as a podiatrist in RSA, they graduate with the skill to manufacture orthotics by hand. In practise, the quality and efficacy of these devices have always been questioned. However, studies have never been conducted to evaluate the efficacy of these devices. This approach drew concern to the researcher as clinical treatments should be evidence-based.

Figure 22 Traditional handmade custom foot orthotics (Merriman.,2009).

5.5. CAD/CAM orthoses

CAD/CAM is an advanced method of manufacturing custom foot orthoses. However, CAD/CAM technology is still presently expensive. Thus, not available to most podiatrists to consider as part of their routine clinical service, even though this technology offers various advantages over traditional methods (Gatt *et al*., 2016). These include accuracy, increased quality, a less messy process, and most importantly, providing faster turnaround time benefitting the patient (Gatt *et al*., 2016). The materials utilised to manufacture CAD/CAM orthoses such as ethylene-vinyl acetate and polyurethane are distinctively different from those employed by traditional methods (Gatt *et al*., 2016). This digital process minimises the time needed to obtain a foot model compared to traditional methods and limits correction errors (Fantini *et al.,* 2017). Despite the scepticism that RSA podiatrists have around this orthotics manufacturing method, this growing technology is gaining evidence for efficacy in various specialities. Studies by Sheykhi-Dolagh et al. (2015) and Kido et al. (2014) conducted abroad support CAD/CAM orthotics' effectiveness.

Figure 23 Computer-Aided Design (CAD) orthotic (Fantini *et al.,* 2017).

5.6 A comparison in the Realignment of Functional Pes Planus between Handmade and Computer-aided design/manufactured (CAD/CAM) foot orthotics.

This study aimed to investigate, document, and compare handmade and CAD/CAM orthotics concerning the effectiveness in the realignment of functional pes planus deformity. It was hypothesized that significant differences were found in realignment / the navicular drop values achieved between both types of orthotic devices. The researcher postulates that this study's findings suggest that both devices would generally realign the foot into typical navicular drop values, highlighting the significant differences between the two manufacturing methods.

The findings indicated for handmade orthotics, the Navicular drop measured in millimetres (mm) of the **Right foot** had realigned within normal limits amongst **86% (43/50)** of participants. However, **14% (7/50)** of participants right foot remained within excessively pronated limits (N.D. greater than 10mm), which meant that the handmade orthotic had failed to correct the deformity adequately or was unable to reduce N.D within normal limits in 14% of the participant's right foot. The Navicular drop measured in millimetres (mm) of the **Left foot** had met normal limits (N.D. less than 10mm) amongst **80% (40/50)** of participants. However, **18% (9/50)** of participants' left foot remained in excessively pronated limits. Which meant 9 participants had their left foot remaining misaligned as these orthotics failed to realign the foot to normal N.D limits.

In summary, it was found that amongst 80% (40/50) of participants' the handmade orthoses had successively realigned both feet, which meant that N.D values were realigned to normal values for both the left and the right foot. However, 20% (10/50), participants' had N.D values that remained abnormal, meaning that for 20% of the participants, the orthoses failed to realign both feet. In fact, of these 10 participants, 6/10 (12%) participants had both their feet remain misaligned, which meant these orthoses failed to correct both feet. In 3/10 (6%), participants had their left foot realigned to normal N.D values, but their right foot remained in abnormal N.D values (misaligned). Lastly, 1/10 (2%) participants had both their feet overcorrected, meaning that the orthoses had changed both feet in a completely different position/ pathology.

The variations in the realignment of pes planus noted in this study are concerning and bring about severe clinical implications; firstly, orthotics' function is to improve foot function, having said this, handmade orthotics are not 100% reliable nor effective. Keeping in mind that these handmade orthotics are dispensed to patients as a treatment for pes planus deformity. According to the Health Professions Council of South Africa (HPCSA) Guidelines for good practice in health care professions: booklet 2:

'*A practitioner may prescribe or supply medicine or a medical device to a patient: Provided that such practitioner has ascertained the diagnosis of the the patient concerned through a personal examination of the patient or by virtue of a report by another practitioner under whose treatment the patient is or has been and such medicine or medical device is clinically indicated,* ***taking into account the diagnosis and the individual prognosis of the patient,*** *and* ***affords the best possible care*** *at a cost-effective rate compared to other available medicines or medical devices, and the patient is informed of such other available medicines or medical devices'.*

If a CFO is deemed a medical device, it should afford the best possible care to the patient. An orthotic that fails to realign a pes planus foot to normal limits is deemed a medical device that does not afford the best possible care to the patient and is therefore unethical and regarded as poor practice. It is postulated that if an orthotic is

manufactured by hand, this hinders the final product's efficacy. If these handmade orthotics fail to realign a pes planus foot to normal limits, this actually predisposes a patient to develop foot-related complications and worsen deformity. Since manufacturing handmade orthotics involves manual skills, there will always be human error, which is detrimental to patient care or clinical outcomes.

The study's findings indicate that the handmade devices had failed to completely realign the pes planus foot amongst all the participants. Moreover, in 20% of these participants, these orthotics either partially realigned one foot and failed to realign both feet or overcorrected the foot into a different foot posture. In 2% of the participants, handmade devices resulted in an overcorrection of the deformity beyond normal N.D limits. Overcorrection effectively meant that the foot was put into a completely new position, i.e., moving the foot from pes planus into a supinated foot posture. This meant that 2% of the handmade orthotics had changed the foot into a completely different foot deformity. The clinical implications of overcorrection have serious adverse effects to the foot, meaning the device has now created a different pathology that had not been present before. It is important to acknowledge if such error is practised clinically, this could result in practitioner litigation.

Literature suggests the possible reason why some handmade orthotics failed to realign the foot was merely due to the disadvantages of handmade orthotics that is the risk of error through mass production or manual technical skills (human error). As mentioned earlier, the disadvantage results hinder the treatment of pes planus, as realignment is not achieved. This may lead to failure of the orthotic device's treatment and function, which may predispose a patient to develop complications of pes planus deformity.

These findings are noteworthy as they suggest a degree of failure of podiatrists' current predominant intervention method to treat pes planus. There have been no studies done by podiatrists to investigate the success rate of handmade orthotics in RSA. Additionally, it is unclear if podiatrists take any pre-intervention and post-intervention measurements to check the effectiveness or lack thereof of orthotic therapy for pes planus. The researcher is a practising podiatrist. In clinical practice, the effectiveness of orthoses is merely based on patient comfort. If the patient

reports that the orthoses fit comfortably, it is then assumed that it is effective. The disadvantage of not having a standardized assessment tool for post-intervention is a constant return of orthotics by patients; a podiatrist would have to constantly adjust these devices until the patient is satisfied and deems the device comfortable. This would mean that for every device dispensed to a patient, comfort would guarantee effectiveness.

The findings indicated for CAD/CAM orthotics were precisely what the researcher had hypothesized: this novel approach of manufacturing orthotics would be accurate in achieving normal N.D limits, and that realignment would be achieved significantly. The findings show that 100% of participants (50/50) had N.D within normal limits achieved by CAD/CAM orthotics for both feet. In fact, the realignment achieved by CAD devices was better than handmade devices. It is noted that none of the participants' feet remained in abnormal N.D limits, nor were any feet overcorrected. Realignment was achieved accurately, possibly due to the advantages of CAD/CAM orthotics' manufacturing process. Some advantages include accuracy, increased quality, and this digital manufacturing process reduces the risk of error. This software, which provides a 3D model of the foot prior to orthotic fabrication, can also assess the patient's foot and the manufactured device before the device is dispensed to the patient, this post-assessment of the orthotic can show all parameters of the foot, arch height, realignment values, pressure distribution even provide a gait analysis. This is where handmade orthotics fall short merely due to the post-assessment being based on human visual gait assessment and patient satisfaction.

In this study, the statistical comparison of the Average Navicular drop measured in millimetres (mm) of the Right and Left foot showed an average N.D variation of 2mm exists between handmade and CAD/CAM orthotics. This meant the 80% of handmade devices that did achieve realignment still offered inadequate realignment as they realigned the foot from 13mm to 8mm. In contrast, CAD/CAM realigned the foot from 13mm to 6mm, deeming CAD/CAM orthotics offer better realignment.

Handmade devices achieved realignment amongst 80% of the participants where and CAD/CAM achieved 100%. Interestingly the average N.D value achieved by handmade orthotics was 8mm, and for CAD/CAM, 6mm from feet that were initially

N.D limits of 13mm without orthotic devices. In essence, this study has proven that orthotics manufactured by CAD/CAM process offer better realignment for functional pes planus in comparison to orthotics manufactured by hand. The study's findings could improve clinical treatment outcomes of pes planus, reduce the risks of developing foot-related complications, and improve patient satisfaction. The findings of the study could also influence undergraduate and postgraduate training.

Studies have shown orthotics' ability to control the amount of navicular drop in patients with pes planus. A study done by Christensen et al. (2013) found a reduction in N.D when wearing these orthotics. On average, these orthotics reduced the N.D by 0.4mm compared to the average N.D without orthotics (Christensen et al., 2013).

Another study by Ki et al. (2008) was undertaken on a Chinese population to compare plantar pressure distribution patterns between foot orthoses generated by the CAD/CAM and those by traditional methods. The results showed that foot orthoses generated by CAD/CAM system provided a pressure distribution pattern similar to those made by the conventional method, except the mid forefoot region where peak pressure was found to be lower in the CAD/CAM approach. In addition, D'Aminco et al. (2015) conducted a pilot study to define a protocol for the off-loading performances and statistical comparison of traditional and CAD/CAM designed foot orthoses in the diabetic foot. Their study found significant statistical improvement in the reduction of pressure by both orthoses. However, their comparisons confirmed that CAD/CAM orthoses achieve better performance concerning traditional ones.

Various studies conducted abroad regarding the use of orthotics for flexible pes planus deformity indicate positive results. In support of this, Kido et al. (2014) proved that there were positive structural changes in the alignment in the bones of the feet achieved by custom orthotics for individuals that present with flexible pes planus. A study by Sheykhi-Dolagh et al. (2015) investigated foot orthoses' influence on foot mobility magnitude and arch height index in individuals with flexible flat feet. Their study found that orthotics brought arch height index close to normal arch height index compared to barefoot alone (Sheykhi-Dolagh et al., 2015). A review article by Douglas (2015) supports orthotic treatment for the adult acquired flat foot. It can be a powerful tool to correct alignment and prevent subluxation of the adult acquired flat

foot. These studies confirmed that some parameters, such as alignment and arch height, were improved by orthotics amongst individuals presenting with flexible flat feet deformity.

Despite the sceptics around CAD/CAM orthotics, this novel method is widely used abroad. It has supporting research for its reliability and efficacy. As alluded to earlier, the method used to manufacture custom foot orthotics is critical in producing effective orthotics. This study's findings have highlighted significant variations between handmade and CAD/CAM orthotics in the realignment of pes planus. This maybe is considered minimal. However, it has a profound effect on the actual final product. The researcher argues that this may explain why the orthotics produced by hand are always uncomfortable for patients, and many devices fail as a treatment plan.

If Podiatrists continue to manufacture orthotics by hand, this predisposes foot-related complications and treatment failure. Therefore, it is important that CAD/CAM be included in undergraduate and postgraduate training to influence clinical practice. This study was designed to provide such preliminary evidence by providing evidence about handmade orthotics' efficacy. The study demonstrated that CAD/CAM orthotics realign a pes plus foot to normal limits amongst all (100%) participants, whereas handmade orthotics failed to. Thus, this intervention might be the best method to achieve 100% realignment in pes planus deformity and may be worth considering as the method for orthotic manufacture in the management of pes planus. The current study findings are in line with the literature and other recent studies and thus provide evidence on CAD/CAM orthotics' efficacy.

In this context, the current study findings might provide critical input and variation in the management of pes planus. Current Podiatric methods of manufacturing orthotics are outdated, and their ability to produce 100% effective orthotics is not guaranteed. Thus, the findings are noteworthy, as they show that CAD/CAM orthotics can accurately realign pes planus foot.

5.4 Conclusion

In this chapter, the main findings of the study have been discussed. Significant variations between handmade and CAD/CAM orthotics have been highlighted.

CHAPTER SIX: SUMMARY AND CONCLUSION

6.1 Introduction

This final chapter provides a summary and conclusion of this research study and dissertation.

6.2 Summary of the research study and dissertation

6.3 Recommendations

Considering the outcomes and findings of this study, the following recommendations are made:

- Podiatrists should be encouraged to utilise CAD/CAM orthotics to treat pes planus as these devices provide optimum realignment/ better clinical outcomes compared to current traditional methods.
- CAD/CAM Technology should be made affordable for podiatrists in RSA.
- There should be local suppliers in RSA for this technology/equipment.
- CAD/CAM training should be offered as a short learning course for those podiatrists who have not had this structured in their undergrad training; since 2020, the University of Johannesburg has invested in full CAD/CAM technology structured in the undergraduate training of Podiatry in RSA.

6.4 Potential contributions of this study

This study produced new literature on the realignment of flexible pes planus with the use of handmade orthotics versus CAD/CAM orthotics. The study highlighted that the traditional Podiatry method of manufacturing orthotics has lower validity and reliability when compared to CAD/CAM methods of manufacture. The study's findings could improve clinical treatment outcomes of pes planus, reduce the risks of developing foot-related complications, and improve patient satisfaction.

Evidence suggests changes to the method of manufacturing orthotics are necessary in order to improve its validity and reliability and significant clinical outcomes. This study highlighted the need for CAD/CAM orthotics to be the goal standard in the

realignment of flexible pes planus as such methods provide reliable clinical outcomes. Advanced technology such as CAD/CAM orthotics may lead the researcher to investigate further the effect of such devices on other foot and lower limb pathologies. Publishing this study could encourage South African podiatrists to merge from practising traditional methods of manufacturing orthotics to advanced methods, i.e., CAD/CAM.

6.5 Limitations

- In this study, the researcher wishes to acknowledge the following challenges and limitations:
- The limited published literature on both manufacturing methods of orthotics, i.e., handmade and CAD/CAM, more specifically in the local South African context, was a challenge faced in completing this study. Most studies that were published are abroad.
- The time spent for handmade orthotics was time-consuming as 50 pairs were manufactured for this study, which delayed the data collection process.

6.6 Proposals for further Studies

- Further research should be done on clinical outcomes/ efficacy of CAD/CAM orthotics for various foot and lower limb disorders.
- A study should be done to compare the realignment of flexible pes planus with CAD/CAM orthotics versus prefabricated orthotics.
- This study could be a longitudinal study with a larger sample size.

6.7 Conclusion

Traditional handmade custom foot orthotics is a conventional approach, widely used among podiatrists, is wholly based on manual activities and craft-based processes that depend on individual podiatrists' skill and expertise that need considerable training and practise to reach optimal results (Fantini *et al.*, 2017). This type of method is one that has the most prolonged existence amongst all other types of methods. Many podiatrists in RSA still utilise this traditional method in which custom foot orthoses are handmade. This approach is also unpleasant for patients

during the cast impression and frequently needs to repeat the process if the orthotics have a poor fit on the patients' foot, thus resulting in time-consuming and material wasting (Fantini *et al.,* 2017). In support of this, Gatt et al. (2016) mention that fabricating custom orthoses manually is time-consuming and requires significant technical ability, thus creating the risk of error.

CAD/CAM orthoses is an advanced method of manufacturing custom foot orthoses. However, this type of technology is still presently expensive and thus not available to the majority of podiatrists to consider as part of their routine clinical service, even though this technology offers various advantages over traditional methods (Gatt *et al*., 2016). Some advantages include accuracy, increased quality, a less messy process, and most importantly, providing faster turnaround time, benefitting the patient (Gatt *et al*., 2016). The materials utilised to manufacture CAD/CAM orthoses such as ethylene-vinyl acetate and polyurethane are distinctively different from those employed by traditional methods (Gatt *et al*., 2016). This digital process minimises the time needed to obtain a foot model when compared to traditional methods and limits correction errors (Fantini *et al.,* 2017).

This study aimed to investigate, document, and compare handmade and CAD/CAM orthotics concerning the effectiveness in the realignment of functional pes planus deformity. It was hypothesized that significant differences were found in realignment / the navicular drop values achieved between both types of orthotic devices. The researcher postulated that this study's findings would suggest that both devices would generally realign the foot into normal navicular drop values, highlighting the significant differences between the two manufacturing methods.

This study showed a degree of failure of the current predominant intervention method used by podiatrists to treat pes planus. Only 80% of the participants had achieved realignment within normal values, whereas in 20% of the participants, handmade orthotics failed to realign the foot. The findings indicated for CAD/CAM orthotics were exactly what the researcher had hypothesized: this novel approach of manufacturing orthotics would be accurate in achieving normal N.D limits, and that realignment would be achieved significantly. All participants (100%) feet were realigned to normal limits by CAD/CAM orthotics.

In this study, the statistical comparison of the Average Navicular drop measured in millimetres (mm) of the Right and Left foot showed an average N.D variation of 2mm exists between handmade and CAD/CAM orthotics. CAD/CAM orthotics offer better realignment compared to those made by hand. Reliability and validity are not guaranteed with handmade orthotics as their efficacy does not have standardised assessment tools in place. The study's findings could improve clinical treatment outcomes of pes planus, reduce the risks of developing foot-related complications, and improve patient satisfaction.

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APPENDIX A: HDC APPROVAL LETTER

FACULTY OF HEALTH SCIENCES

HIGHER DEGREES COMMITTEE

HDC-01-17- 2018

20 April 2018

TO WHOM IT MAY CONCERN:

STUDENT: MOOTHEE, M
STUDENT NUMBER: 200575054

TITLE OF RESEARCH PROJECT: Hand- made versus Computer Aided Design Orthotics for Realignment of Pes Planus: A Comparative Study

DEPARTMENT OR PROGRAMME: PODIATRY

SUPERVISOR: Mr S Ntuli **CO-SUPERVISOR:** Prof C Lambert

The Faculty Higher Degrees Committee has scrutinised your research proposal and concluded that it complies with the approved research standards of the Faculty of Health Sciences; University of Johannesburg.

The HDC would like to extend their best wishes to you with your postgraduate studies

Yours sincerely,

Prof Y Coopoo
Chair: Faculty of Health Sciences HDC
Tel: 011 559 6944
Email: yogac@uj.ac.za

APPENDIX B: REC APPROVAL LETTER

FACULTY OF HEALTH SCIENCES

RESEARCH ETHICS COMMITTEE
NHREC Registration no: REC-241112-035

REC-01-17- 2018

20 April 2018

TO WHOM IT MAY CONCERN:

STUDENT: **MOOTHEE, M**
STUDENT NUMBER: **200575054**

TITLE OF RESEARCH PROJECT: Hand- made versus Computer Aided Design Orthotics for Realignment of Pes Planus: A Comparative Study

DEPARTMENT OR PROGRAMME: PODIATRY

SUPERVISOR: Mr S Ntuli **CO-SUPERVISOR:** Prof C Lambert

The Faculty Research Ethics Committee has scrutinised your research proposal and confirm that it complies with the approved ethical standards of the Faculty of Health Sciences; University of Johannesburg.

The REC would like to extend their best wishes to you with your postgraduate studies.

Yours sincerely,

Prof C Stein
Chair : Faculty of Health Sciences REC
Tel: 011 559 6564
Email: cstein@uj.ac.za

APPENDIX C: PERMISSION LETTER TO HEAD OF DEPARTMENT OF PODIATRY

P.O.Box 353
Kiasha Park
1829

The Head of Department of Podiatry
Mr S. Ntuli
University of Johannesburg

Permission requested for research

As partial fulfilment of a Master's degree, I am conducting a study to ***Compare the difference in realignment of pes planus deformity with the use of traditional handmade orthoses versus computer aided fabricated orthoses.***

For purposes of data collection, Patients with a diagnosis of pes planus consulting the University of Johannesburg, Podiatry Clinic will be recruited and requested to participate in the study. I am writing this letter to request permission to access the Podiatry Clinic to recruit potential participants for the study.

By signing this permission letter, you are hereby granting me permission to conduct this study as discussed above.

Permission Granted	Yes	No
	×	

_____ 20/04/2018

Mr S. Ntuli Date

Your co-operation is highly appreciated.
Yours Faithfully

Melissa Moothee

APPENDIX D: RESEARCH STUDY INFORMATION LETTER

DEPARTMENT OF PODIATRY
RESEARCH STUDY INFORMATION LETTER

Good Day

The researcher, MELISSA MOOTHEE **WOULD LIKE TO INVITE YOU TO PARTICIPATE** in a research study to compare the realignment of pes planus (Flat foot) deformity with the use of traditional handmade orthoses versus computer aided fabricated orthoses.

Before you decide on whether to participate, I would like to explain to you why the research is being done and what it will involve for you. **I will go through the information letter with you and answer any questions you have.** This should take about 10 to 20 minutes. The study is part of a research project being completed for a MASTER'S DEGREE in PODIATRY through the University of Johannesburg.

THE PURPOSE OF THIS STUDY is to compare the realignment of pes planus (Flat foot) deformity with the use of traditional handmade orthoses versus computer aided fabricated orthoses.

Below, I have compiled a set of questions and answers that I believe will assist you in understanding the relevant details of participation in this research study. If you have any further questions I will be happy to answer them for you.

DO I HAVE TO TAKE PART? No, you don't have to. It is up to you to decide to participate in the study. I will describe the study and go through this information sheet. If you agree to take part, I will ask you to sign a consent form.

WHAT EXACTLY WILL I BE EXPECTED TO DO IF I AGREE TO PARTICIPATE? You will be required to have both your feet clinically evaluated for the degree of flat foot and thereafter both your feet will be casted. There is no pain or discomfort associated with this procedure and it will take about 10 minutes of your time.

WHAT WILL HAPPEN IF I WANT TO WITHDRAW FROM THE STUDY? If you decide to participate, you are free to withdraw your consent without giving a reason and without any consequences. If you wish to withdraw your consent, you must inform me during the initial clinical evaluation and casting.

IF I CHOOSE TO PARTICIPATE, WILL THERE BE ANY EXPENSES FOR ME, OR PAYMENT DUE TO ME: You will not incur any expenses by participating in this study, nor will any payment be made to you

RISKS INVOLVED IN PARTICIPATION: There are no risks involved with this study

BENEFITS INVOLVED IN PARTICIPATION: There are direct benefits associated with taking part in this study.

WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL? Yes, no names or any person identifying data will be captured as part of the study. Each participant will be allocated a number and as such there will be no way to identify each participant. Soft data generated as part of this study will be kept in password protected folders and hard data will be kept in a locked cabinet. Only the researcher and research supervisors will be authorized to use and/or disclose your anonymised information in connection with this research study. Any other person wishing to work with your anonymised information as part of the research process (e.g. an independent data coder) will be required to sign a confidentiality agreement before being allowed to do so.

WILL MY TAKING PART IN THIS STUDY BE ANONYMOUS? Yes. Anonymous means that your personal details will not be recorded anywhere by me. As a result, it will not be possible for me or anyone else to identify you once these have been submitted.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY? The results will be written into a research report that will be assessed. In some cases, results may also be published in a scientific journal. In either case, you will not be identifiable in any documents, reports or publications. You will be given access to the study results if you would like to see them, by contacting me.

WHO IS ORGANISING AND FUNDING THE STUDY? The study is being organized by me, under the guidance of my research supervisor at the Department of Podiatry in the University of Johannesburg. This study is receiving funding from the researcher.

WHO HAS REVIEWED AND APPROVED THIS STUDY? Before this study could start, it was reviewed by the HDC and REC to protect your interests. This review was done first by the Higher Degrees Committee, and then secondly by the Faculty of Health Sciences Research Ethics Committee at the University of Johannesburg. In both cases, the study was approved.

WHAT IF THERE IS A PROBLEM? If you have any concerns or complaints about this research study, its procedures or risks and benefits, you should ask the researcher. You should contact the researcher at any time if you feel you have any concerns about being a part of this study. Contact details are:

Prof. C Stein
REC Chair
(011) 599 6564
cstein@uj.ac.za

Melissa Moothee
Researcher
084 542 0192 / (011) 559 6593
mmoothee@uj.ac.za

You may also contact the research supervisors:

Mr S Ntuli
sntuli@uj.ac.za
(011) 559 6910

Prof C. Lambert
clambert@uj.ac.za
(011) 559 6257

APPENDIX E: RESEARCH CONSENT FORM

DEPARTMENT OF PODIATRY
RESEARCH CONSENT FORM

HANDMADE VERSES COMPUTER -AIDED DESIGN ORTHOTICS FOR REALIGNMENT OF PES PLANUS: A COMPARITIVE STUDY

Please initial each box below:

☐ I confirm that I have read and understand the information letter for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

☐ I understand that my participation is voluntary and that I am free to withdraw from this study prior to data collection without giving any reason and without any consequences to me.

☐ I agree to take part in the above study.

Participant: Date:

Researcher Date:

APPENDIX F: DATA SHEET

FOOT POSTURE INDEX DATA SHEET

Patient Number:	
Contact details:	

	FACTOR	PLANE	SCORE 1 Date_____ Comment_____		SCORE 2 Date_____ Comment_____		SCORE 3 Date_____ Comment_____	
			Left -2 to +2	*Right* -2 to +2	*Left* -2 to +2	*Right* -2 to +2	*Left* -2 to +2	*Right* -2 to +2
Rearfoot	Talar head palpation	*Transverse*						
Rearfoot	Curves above and below the lateral malleolus	*Frontal/ transverse*						
Rearfoot	Inversion/eversion of the calcaneus	*Frontal*						
Forefoot	Prominence in the region of the TNJ	*Transverse*						
Forefoot	Congruence of the medial longitudinal arch	*Sagittal*						
Forefoot	Abd/adduction forefoot on rearfoot	*Transverse*						
	TOTAL							

Reference values
Normal = 0 to +5
Pronated = +6 to +9, Highly pronated 10+
Supinated = -1 to –4, Highly supinated –5 to -12

THE NAVICULAR DROP TEST DATA SHEET

Patient Number: **Contact details:**						
Factor	**SCORE 1 :without orthotics Date_____**		**SCORE 2 :Handmade orthotics (A) Date_____**		**Score 3: CAD/CAM orthotics (B)**	
Navicular Drop (mm)	***Left***	***Right***	***Left***	***Right***	***Left***	***Right***

Reference values (Brody,1982)
Normal = 5mm – 9mm
Excessively Pronated= < 10mm
Supinated= 0-4mm

APPENDIX G: TURNITIN REPORT

mtech

ORIGINALITY REPORT

5%	%	5%	%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Tulaya Prachgosin, Wipawan Leelasamran, Pruittikorn Smithmaitrie, Surapong Chatpun. "Effect of total-contact orthosis on medial longitudinal arch and lower extremities in flexible flatfoot subjects during walking", Prosthetics and Orthotics International, 2017 Publication	<1%
2	Cyntia Rogean De Baptista, Adriana H. Nascimento-Elias, Beatriz Garcia, Amanda Testa et al. "Physical function and performance measures of children and adolescents with Charcot-Marie-Tooth disease", Physiotherapy Theory and Practice, 2019 Publication	<1%
3	"Contents List", Gait & Posture, 2015 Publication	<1%
4	Yosuke Maruyama, Katsutoshi Itsukaichi, Satoko Tanabe, Takayuki Nakagomi, Tomohiro Matsuyama, Hiroyuki Sasaki. "Correlation between radiographic morphometry and body	<1%